45/pt.1-199/990

code of federal regulations

Public Welfare

45

PARTS 1 TO 199

Revised as of October 1, 1990

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Public Welfare

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PARTS 1 TO 199

Revised as of October 1, 1990

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AND FUTURE EFFECT

AS OF OCTOBER 1, 1990

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Cite this Code: **CFR**

To cite the regulations in this volume use title, part and section number. Thus, **45 CFR 1.1** *refers to title 45, part 1, section 1.*

Explanation

The Code of Federal Regulations is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. The Code is divided into 50 titles which represent broad areas subject to Federal regulation. Each title is divided into chapters which usually bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas.

ISSUE DATES

Each volume of the Code is revised at least once each calendar year and issued on a quarterly basis approximately as follows:

Title 1 through Title 16	**as of January 1**
Title 17 through Title 27	**as of April 1**
Title 28 through Title 41	**as of July 1**
Title 42 through Title 50	**as of October 1**

The appropriate revision date is printed on the cover of each volume.

LEGAL STATUS

The contents of the Federal Register are required to be judicially noticed (44 U.S.C. 1507). The Code of Federal Regulations is prima facie evidence of the text of the original documents (44 U.S.C. 1510).

HOW TO USE THE CODE OF FEDERAL REGULATIONS

The Code of Federal Regulations is kept up to date by the individual issues of the Federal Register. These two publications must be used together to determine the latest version of any given rule.

To determine whether a Code volume has been amended since its revision date (in this case, October 1, 1990), consult the "List of CFR Sections Affected (LSA)," which is issued monthly, and the "Cumulative List of Parts Affected," which appears in the Reader Aids section of the daily Federal Register. These two lists will identify the Federal Register page number of the latest amendment of any given rule.

EFFECTIVE AND EXPIRATION DATES

Each volume of the Code contains amendments published in the Federal Register since the last revision of that volume of the Code. Source citations for the regulations are referred to by volume number and page number of the Federal Register and date of publication. Publication dates and effective dates are usually not the same and care must be exercised by the user in determining the actual effective date. In instances where the effective date is beyond the cut-off date for the Code a note has been inserted to reflect the future effective date. In those instances where a regulation published in the Federal Register states a

date certain for expiration, an appropriate note will be inserted following the text.

OMB CONTROL NUMBERS

The Paperwork Reduction Act of 1980 (Pub. L. 96-511) requires Federal agencies to display an OMB control number with their information collection request. Many agencies have begun publishing numerous OMB control numbers as amendments to existing regulations in the CFR. These OMB numbers are placed as close as possible to the applicable recordkeeping or reporting requirements.

OBSOLETE PROVISIONS

Provisions that become obsolete before the revision date stated on the cover of each volume are not carried. Code users may find the text of provisions in effect on a given date in the past by using the appropriate numerical list of sections affected. For the period before January 1, 1973, consult either the List of CFR Sections Affected, 1949-1963, or 1964-1972, published in three separate volumes. For the period beginning January 1, 1973, a "List of CFR Sections Affected" is published at the end of each CFR volume.

CFR INDEXES AND TABULAR GUIDES

A subject index to the Code of Federal Regulations is contained in a separate volume, revised annually as of January 1, entitled CFR INDEX AND FINDING AIDS. This volume contains the Parallel Table of Statutory Authorities and Agency Rules (Table I), and Acts Requiring Publication in the Federal Register (Table III). A list of CFR Titles, Chapters, and Parts and an alphabetical list of agencies publishing in the CFR are also included in this volume.

An index to the text of "Title 3—The President" is carried within that volume.

The Federal Register Index is issued monthly in cumulative form. This index is based on a consolidation of the "Contents" entries in the daily Federal Register.

A List of CFR Sections Affected (LSA) is published monthly, keyed to the revision dates of the 50 CFR titles.

REPUBLICATION OF MATERIAL

There are no restrictions on the republication of material appearing in the Code of Federal Regulations.

INQUIRIES AND SALES

For a summary, legal interpretation, or other explanation of any regulation in this volume, contact the issuing agency. Inquiries concerning editing procedures and reference assistance with respect to the Code of Federal Regulations may be addressed to the Director, Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408 (telephone 202-523-3517). Sales are handled exclusively by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402 (telephone 202-783-3238).

MARTHA L. GIRARD,
Director,
Office of the Federal Register.

October 1, 1990.

THIS TITLE

Title 45—PUBLIC WELFARE is composed of four volumes. The parts in these volumes are arranged in the following order: Parts 1-199, 200-499, 500-1199, and 1200 to end. Volume one (Parts 1-199) contains all current regulations issued under Subtitle A—Department of Health and Human Services, General Administration. Volume two (Parts 200-499) contains all current regulations issued under Chapter II—Office of Family Assistance (Assistance Programs), Family Support Administration, Department of Health and Human Services, Chapter III—Office of Child Support Enforcement (Child Support Enforcement Program), Family Support Administration, Department of Health and Human Services, and Chapter IV—Office of Refugee Resettlement, Family Support Administration, Department of Health and Human Services. Volume three (Parts 500-1199) contains all current regulations issued under Chapter V—Foreign Claims Settlement Commission of the United States, Department of Justice, Chapter VI—National Science Foundation, Chapter VII—Commission on Civil Rights, Chapter VIII—Office of Personnel Management, Chapter X—Office of Community Services, Family Support Administration, Department of Health and Human Services, and Chapter XI—National Foundation on the Arts and the Humanities. Volume four (Part 1200-End) contains all current regulations issued under Chapter XII—ACTION, Chapter XIII—Office of Human Development Services, Department of Health and Human Services, Chapter XVI—Legal Services Corporation, Chapter XVII—National Commission on Libraries and Information Science, Chapter XVIII—Harry S Truman Scholarship Foundation, Chapter XX—Commision on the Bicentennial of the United States Constitution, Chapter XXI—Commission of Fine Arts, and Chapter XXII—Christopher Columbus Quincentenary Jubilee Commission. The contents of these volumes represent all of the current regulations codified under this title of the CFR as of October 1, 1989.

A subject index to 45 CFR Parts 680-684 appears in the Finding Aids section of the volume containing Parts 500-1199. Those amendments to Part 801—Voting Rights Program, Appendixes A, B, and D, which apply to Texas also appear in Spanish following Appendix D.

Redesignation tables appear in the Finding Aids section of each volume. A derivation table relating to the disposition of sections in Part 101 appears in the first volume.

For this volume Linda L. Jones was Chief Editor. The Code of Federal Regulations publication program is under the direction of Richard L. Claypoole, assisted by Alomha S. Morris.

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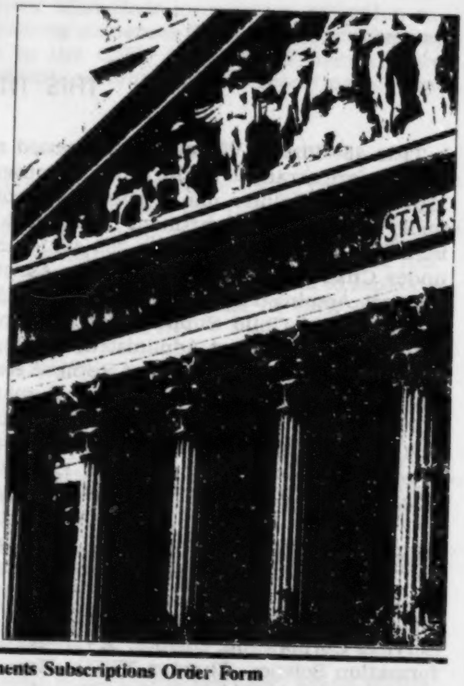

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Title 45—Public Welfare

(This book contains Parts 1 to 199)

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SUBTITLE A—DEPARTMENT OF HEALTH AND HUMAN SERVICES, GENERAL ADMINISTRATION

PART 1—HHS'S REGULATIONS

§ 1.1 Location of HHS regulations.

Regulations for HHS's programs and activities are located in several different titles of the Code of Federal Regulations:

- Regulations having HHS-wide application or which the Office of the Secretary administers are located in Parts 1-99 of Title 45.
- Health regulations are located at Parts 1-399 of Title 42.
- Health care financing regulations are located at Parts 400-499 of Title 42. These include regulations for Medicare and Medicaid.
- Human development services regulations are located at Parts 200-299 and 1300-1399 of Title 45. These include regulations for Head Start, social services, social and nutrition services for older persons, rehabilitative services, developmental disabilities services, Native American programs, and various programs relating to families and children.
- Social Security regulations are located at Parts 400-499 of Title 20.
- Food and Drug regulations are located at Parts 1-1299 of Title 21.
- Procurement (contract) regulations are located at Chapter 3 of Title 41.

Each volume of the Code contains an index of its parts.

(5 U.S.C. 301)

[44 FR 61598, Oct. 26, 1979, as amended at 48 FR 35099, Aug. 3, 1983]

§ 1.2 Subject matter of Office of the Secretary regulations in Parts 1-99.

This subject matter of the regulations in Parts 1-99 of this title includes:

- *Civil rights/nondiscrimination:* Parts 80, 81, 83, 84, 86, 90.
- *Protection of human subjects:* Part 46.
- *Day care requirements:* Part 71.
- *Information, privacy, advisory committees:* Parts 5, 5a, 5b, 11, 17, 99.
- *Personnel:* Parts 50, 57, 73, 73a.
- *Grants and letter of credit administration, property, hearing rights:* Parts 10, 12, 15, 16, 74, 75, 77, 95.
- *Claims:* Parts 30, 35.
- *Inventions and patents:* Parts 6, 7, 8.
- *Miscellaneous:* Parts 3, 4, 9, 67.

(5 U.S.C. 301)

[50 FR 781, Jan. 7, 1985, as amended at 52 FR 28658, July 31, 1987]

PART 2—TESTIMONY BY EMPLOYEES AND PRODUCTION OF DOCUMENTS IN PROCEEDINGS WHERE THE UNITED STATES IS NOT A PARTY

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2.4 Procedures when voluntary testimony is requested or when an employee is subpoenaed.
2.5 Subpoenas duces tecum.
2.6 Certification and authentication of records.

AUTHORITY: 5 U.S.C. 301, 5 U.S.C. 552.

SOURCE: 52 FR 37146, Oct. 5, 1987, unless otherwise noted.

§ 2.1 Scope, purpose, and applicability.

(a) This part sets forth rules to be followed when a Department of Health and Human Services employee, other than an employee of the Food and Drug Administration, is requested or subpoenaed to provide testimony, in a deposition, trial, or other similar proceeding, concerning information acquired in the course of performing official duties or because of the employee's official capacity. This part also sets forth procedures for the handling of subpoenas duces tecum and other requests for any document in the possession of the Department of Health and Human Services other than the Food and Drug Administration, and to requests for certification of copies of documents. Separate regulations, 21 CFR part 20 and 20 CFR part 401, govern the Food and Drug Administration and requests for certain information maintained by the Social Security Administration, and those regulations are not affected by this part.

(b) It is the policy of the Department of Health and Human Services to provide information, data, and records to non-federal litigants to the same extent and in the same manner that they are available to the general public. The availability of Department of Health and Human Services' employees to testify in litigation not involving Federal parties is governed by the Department of Health and Human Services' policy on maintaining strict impartiality with respect to private litigants and to minimize the disruption of official duties.

(c) This part applies to state and local court, administrative, and legislative proceedings and Federal court and administrative proceedings.

(d) This part does not apply to:

(1) Any civil or criminal proceedings where the United States, the Department of Health and Human Services, and any agency thereof, or any other Federal agency is a party.

(2) Congressional requests or subpoenas for testimony or documents.

(3) Consultative services and technical assistance provided by the Department of Health and Human Services, or any agency thereof, in carrying out its normal program activities.

(4) Employees serving as expert witnesses in connection with professional and consultative services as approved outside activities in accordance with 45 CFR 73.735-704 and 73.735-708. (In cases where employees are providing such outside services, they must state for the record that the testimony represents their own views and does not necessarily represent the official position of the Department of Health and Human Services.)

(5) Employees making appearances in their private capacity in legal or administrative proceedings that do not relate to the Department of Health and Human Services (such as cases arising out of traffic accidents, crimes, domestic relations, etc.) and not involving professional and consultative services.

(6) Any matters covered in 21 CFR part 20, involving the Food and Drug Administration, and 20 CFR part 401, involving the Social Security Administration.

(7) Any civil or criminal proceedings in State court brought on behalf of the Department of Health and Human Services.

[52 FR 37146, Oct. 5, 1987, as amended at 55 FR 4611, Feb. 9, 1990]

§ 2.2 Definitions.

Agency Head refers to the head of the relevant operating division or other major component of the Department of Health and Human Services, or his or her delegatees. For each component of the Department, the Agency Head for the purposes of this part is as follows:

(1) Office of the Secretary—Assistant Secretary for Management and Budget;

(2) Office of Human Development Services—Assistant Secretary for Human Development Services;

(3) Public Health Service—Assistant Secretary for Health;

(4) Health Care Financing Administration—Administrator;

(5) Family Support Administration—Assistant Secretary for Family Support;

(6) Social Security Administration—Commissioner; and

(7) Office of the Inspector General—Inspector General.

Employee includes commissioned officers in the Public Health Service Commissioned Corps, as well as regular and special Department of Health and Human Services employees (except employees of the Food and Drug Administration), and any employees of health insurance intermediaries and carriers performing functions under agreements entered into pursuant to sections 1816 and 1842 of the Social Security Act, 42 U.S.C. 1395h, 1395u.

Testify and testimony includes both in-person, oral statements before a court, legislative or administrative body and statements made pursuant to depositions, interrogatories, declarations, affidavits, or other formal participation.

[52 FR 37146, Oct. 5, 1987, as amended at 55 FR 4611, Feb. 9, 1990]

§ 2.3 Policy on presentation of testimony and production of documents.

(a) No Department of Health and Human Services employee may provide testimony or produce documents in any proceedings to which this part applies concerning information acquired in the course of performing official duties or because of the employee's official relationship with the Department of Health and Human Services unless authorized by the Agency head pursuant to this part based on a determination by the Agency head, after consultation with the Office of the General Counsel, that compliance with the request would promote the objectives of the Department of Health and Human Services.

(b) The Office of the General Counsel will request the assistance of the Department of Justice where necessary to represent the interests of the Department of Health and Human Services and its employees under this part.

§ 2.4 Procedures when voluntary testimony is requested or when an employee is subpoenaed.

(a) All requests for testimony by a Department of Health and Human Services employee in his or her official capacity and not subject to the exceptions set forth in § 2.1(d), of this part, must be in writing and must state the nature of the requested testimony, why the information sought is unavailable by any other means, and the reasons why the testimony would be in the interests of the Department of Health and Human Services or the Federal Government.

(b) If the Agency head denies approval to comply with a subpoena for testimony, or if the Agency head has not acted by the return date, the employee will appear at the stated time and place, unless advised by the Office of the General Counsel that responding to the subpoena would be inappropriate (in such circumstances as, for example, an instance where the subpoena was not validly issued or served, where the subpoena has been withdrawn, or where discovery has been stayed), produce a copy of these regulations, and respectfully decline to testify or produce any documents on the basis of these regulations.

§ 2.5 Subpoenas duces tecum.

(a) Subpoenas duces tecum for records of the Department of Health and Human Services shall be deemed a request for records under the Freedom of Information Act and shall be handled pursuant to the rules governing public disclosure established in 45 CFR Part 5.

(b) Whenever a subpoena duces tecum, in appropriate form, has been lawfully served upon a Department of Health and Human Services' employee commanding the production of any record, such employee, after consultation with the Office of the General Counsel, shall appear in response thereto, respectfully decline to produce the record(s) on the ground that it is prohibited by this section, and state that the production of the record(s) involved will be handled by the procedures and disclosure rules established in 45 CFR Part 5.

§ 2.6 Certification and authentication of records.

Upon request, Department of Health and Human Services' agencies will certify the authenticity of copies of records that are to be disclosed pursuant to 45 CFR Part 5 and will authenticate copies of records previously disclosed. Fees for such certification are set forth in 45 CFR 5.43(e).

[52 FR 37146, Oct. 5, 1987, as amended at 55 FR 4611, Feb. 9, 1990]

PART 3—CONDUCT OF PERSONS AND TRAFFIC ON THE NATIONAL INSTITUTES OF HEALTH FEDERAL ENCLAVE

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3.61 Penalties.

AUTHORITY: 40 U.S.C. 318–318d, 486; Delegation of Authority, 33 FR 604.

SOURCE: 55 FR 2068, Jan. 22, 1990, unless otherwise noted.

Subpart A—General

§ 3.1 Definitions.

Director means the Director or Acting Director of the National Institutes of Health (NIH), or other officer or employee of NIH to whom the authority involved has been delegated.

Enclave means, unless the context requires a different meaning, the area, containing about 318 acres, acquired by the United States in several parcels in the years 1935 through 1983, and any further future acquisitions, comprising the National Institutes of Health located in Montgomery County, Maryland, over which the United States acquired exclusive jurisdiction under the Act of March 31, 1953, Chapter 158 (1953 Maryland Laws 311).

Police officer means a uniformed or non-uniformed police officer appointed under a delegation of authority to the Director under Title 40 United States Code section 318 or 318d; any other Federal law enforcement officer; and any other person whose law enforcement services are secured by contract, or upon request or deputation from a State or local law enforcement agency.

§ 3.2 Applicability.

(a) The regulations in this part apply to all areas in the enclave and to all persons on or within the enclave, except as otherwise provided.

(b) The regulations in this part do not apply to occupants, their visitors, and other authorized persons in areas used as living quarters:

(1) When specifically made inapplicable, and

(2) In the case of the following provisions: § 3.24 Parking permits; § 3.25 Servicing of vehicles; § 3.42 Hobbies and sports; and § 3.42(f) Smoking.

(c) All regulations in this part are in addition to the provisions in the United States Code, including title 18 relating to crimes and criminal procedure, and title 21 relating to food and drugs, which apply:

(1) Without regard to the place of the offense, or

(2) To areas (such as the enclave) subject to the "special maritime and territorial jurisdiction of the United States," as defined in Title 18 United States Code section 7.

(d) In accordance with the Assimilative Crimes Act (18 U.S.C. 13), whoever is found guilty of an offense which, although not made punishable by any act of Congress, nor any provision of these regulations, would be punishable if committed within the State of Maryland, shall be guilty of a like offense and subject to a like punishment. In the event of an irreconcilable conflict between a provision of this part and a Maryland statute governing the identical subject matter, this part shall control.

(e) *Federal criminal Statutes which apply.* The following Federal criminal statutes in the United States Code apply to Federal enclaves and elsewhere without regard to the place of the offense. This listing is provided solely for the information of the public and is not all-inclusive. The omission of other Federal statutes does not mean that such other statutes do not apply. In any given situation, the cited statutory provisions and any amendments in effect when the alleged offense occurred shall determine the specifics of the offense, applicability, and penalty.

Subject	U.S. Code	Provides generally	Maximum penalty
1. By force or threat of force, willful injury, intimidation or interference with, or attempts to injure, intimidate or interfere with, a person from participating in or enjoying any benefit, service, privilege, program, facility, or activity, provided by or administered by the U.S., and engaging in certain other Federal protected activities.	18 U.S.C. 245	Prohibits	Not involving death or bodily injury: Imprisonment one year and/or $1,000 fine.
2. Malicious destruction or damage, by an explosive, to a building or other property owned, possessed, used, or leased by the U.S., U.S. agency, or any organization receiving Federal financial assistance.	18 U.S.C. 844(f)	Prohibits	First offense not involving death or personal injury: Imprisonment 10 years and/or $10,000 fine and seizure and forfeiture of explosive materials.
3. Possession of explosive in buildings owned, possessed, used, or leased by U.S. or U.S. agency.	18 U.S.C. 844(g)	Prohibits, except with written consent of the agency.	Imprisonment one year and/or $1,000 fine and seizure and forfeiture of explosive materials.
4. Use of or carrying an explosive to commit, or during commission of, a felony prosecutable in a U.S. court.	18 U.S.C. 844(h)	Prohibits	First offense: Imprisonment 10 years and seizure and forfeiture of explosive materials.
5. Use of or carrying a firearm during and in relation to any crime of violence prosecutable in a U.S. court.	18 U.S.C. 924(c)	Prohibits	First offense: Imprisonment 5 years and $5,000 fine and seizure and forfeiture of firearm and ammunition.
6. Manufacture, distribution, dispensing, or possession with intent to do these acts, of narcotics and other controlled substances and counterfeit substances.	21 U.S.C. 841, 842, 843, 845	Prohibits, except as authorized by the Controlled Substances Act (generally 21 U.S.C. 801–904).	First offense: Imprisonment 20 years and/or $250,000 fine depending on the amount and kind of substance (twice the above penalties for distribution by a person at least 18 years of age to one under age 21).
7. Simple possession of narcotics or other controlled substances.	21 U.S.C. 844	Prohibits, unless substance obtained directly, or pursuant to prescription or order, from a practitioner, acting in the course of professional practice, or as otherwise authorized under the Controlled Substances Act.	First offense: Imprisonment 1 year and/or $5,000 fine.

(f) *Maryland criminal statutes that apply.* The matters described in this paragraph are governed, in whole or in part, by the current version of the cited Maryland criminal statutory provisions, which are made Federal criminal offenses under the Assimilative Crimes Act (18 U.S.C. 13). This listing sets forth areas of conduct particularly relevant to the enclave and is provided solely for the information of the public. The list is not all-inclusive and omission of other Maryland criminal statutes does not mean that such other statutes are not assimilated as Federal offenses under the Act. Generally, other Maryland criminal statutes will apply on the enclave, by force of the Act, unless superseded by Federal Law or a given provision of this part. In any given situation, the cited statutory provisions and any amendments in effect when the alleged offense occured shall determine the specifics of the offense, applicability, and penalty.

Subject	Maryland code annotated	Provides generally	Maximum penalty
1. Pedestrian right-of-way	Transportation, Sec. 21-502	Pedestrians have the right-of-way in crosswalks and certain other areas. Subject to certain limitations.	Imprisonment 2 months and/or $500 fine.
	Sec. 21-511	Blind, partially blind, or hearing impaired pedestrians have the right-of-way at any crossing or intersection. Subject to certain limitations.	$500 fine.
2. Drivers to exercise due care	Transportation, Sec. 21-504	Drivers shall exercise due care to avoid colliding with pedestrians, children and incapacitated individuals.	$500 fine.
3. Driving while intoxicated, under the influence of alcohol and/or a drug or controlled substance.	Transportation, Sec. 21-902	Prohibits	Sec. 21-902(a) (driving while intoxicated, first offense): Imprisonment 1 year and/or $1,000 fine. Sec. 21-902 (b), (c), (d) (driving under the influence): Imprisonment 2 months and/or $500 fine.
4. Unattended motor vehicles	Transportation, Sec. 21-1101	Prohibits leaving motor vehicles unattended unless certain precautions are taken.	$500 fine.
5. Carrying or wearing certain concealed weapons (other than handguns) or openly with intent to injure.	Article 27, Sec. 36	Prohibits, except for law enforcement personnel or as a reasonable precaution against apprehended danger.	Imprisonment 3 years or $1,000 fine.
6. Unlawful wearing, carrying, or transporting a handgun, whether concealed or openly.	Article 27, Sec. 36B	Prohibits except by law enforcement personnel or with permit.	First offense and no prior related offense: Imprisonment 3 years and/or $2,500 fine.
7. Use of handgun or concealable antique firearm in commission of felony or crime of violence.	Article 27, Sec. 36B	Prohibits	Imprisonment 20 years.
8. Disturbance of the peace	Article 27, Sec. 122	Prohibits acting in a disorderly manner in public places.	Imprisonment 30 days and/or $500 fine.
9. Gambling	Article 27, Secs. 240, 245	Prohibits betting, wagering and gambling, and certain games of chance (does not apply to vending or purchasing lottery tickets authorized under State law in accordance with approved procedures).	Sec. 240: Imprisonment one year and/or $1,000 fine. Sec. 245: Imprisonment 2 years and/or $100 fine.

§ 3.3 Compliance.

A person must comply with the regulations in this part; with all official signs; and with the lawful directions or orders of a police officer or other authorized person, including traffic and parking directions.

§ 3.4 False reports and reports of injury or damage.

A person may not knowingly give any false or fictitious report concerning an accident or violation of the regulations of this part or any applicable Federal or Maryland statute to any person properly investigating an accident or alleged violation. All incidents resulting in injury to persons or willful damage to property in excess of $100.00 (one hundred dollars) in value must be reported by the persons involved to the Police Office as soon as possible. The Police Office's main location and telephone number is: Building 31, Room B3BN10; (301) 496-5685.

§ 3.5 Lost and found, and abandoned property.

Lost articles which are found on the enclave, including money and other personal property, together with any identifying information, must be deposited at the Police Office or with an office (such as the place where found) which may likely have some knowledge of ownership. If the article is deposited with an office other than the Police Office and the owner does not claim it within 30 days, it shall be deposited at the Police Office for further disposition in accordance with General Services Administration regulations (41 CFR part 101-48). Abandoned, or other unclaimed property and, in the absence of specific direction by a court, forfeited property, may be so identified by the Police Office and sold in accordance with 41 CFR 101-45.304-1 and 101-45.304-2.

§ 3.6 Nondiscrimination.

A person may not discriminate by segregation or otherwise against another person because of age, color, creed, handicap, national origin, race or sex, in furnishing or by refusing to furnish to that person the use of any facility of a public nature, including all services, privileges, accommodations, and activities provided within the enclave. (Title 18 United States Code section 245 prohibits, by use of force or threat of force, willful injury, intimidation, or interference with, a person from participating in or enjoying any benefit, service, privilege, program, facility, or activity provided by or administered by the United States, attempts to do these acts, and engaging in certain other activities.)

Subpart B—Traffic Regulations

§ 3.21 Emergency vehicles.

A person must yield the right of way to an emergency vehicle operating its siren or flashing lights.

§ 3.22 Request for identification.

Upon request by a police officer, a person involved in any of the following situations must provide identification, for example, by exhibiting satisfactory credentials (such as an employment identification card or driver's license):

(a) A traffic accident within the enclave;

(b) The police officer reasonably believes that the individual is engaged in, or has engaged in, criminal conduct or a violation of the regulations of this part; or

(c) The enclave or a portion of the enclave is not open to the public (see § 3.41).

A driver of a motor vehicle involved in an accident within the enclave shall also exhibit, upon the request of a police officer, the owner's registration card or other satisfactory proof of ownership.

§ 3.23 Parking.

(a) A person may not stand (vehicle stopped, with or without, an occupant), or park a motor vehicle or other vehicle:

(1) In a lane, space, or area not designated by a sign for parking, and/or standing;

(2) On a sidewalk;

(3) Within an intersection or crosswalk;

(4) within 10 feet of a fire hydrant, 5 feet of a driveway, or 20 feet of a stop

sign, crosswalk, or traffic control signal;

(5) In a double-parked position;

(6) At a curb painted yellow;

(7) On the side of a street facing oncoming traffic;

(8) In a position that would obstruct traffic;

(9) For a period in excess of 24 hours, except at living quarters, or with the approval of the Police Office.

(b) A person must park bicycles, motorbikes, and similar vehicles only in designated areas, and may not bring these vehicles inside buildings.

(c) A visitor must park in an area identified for that purpose by posted signs or similar instructions, such as "visitor parking" and "reserved for visitors".

(d) A person may not drive or park an unauthorized motor vehicle on a grassy, or any other unpaved, area without the approval of the Police Office.

§ 3.24 Parking permits.

Except for visitor parking, a person may not park a motor vehicle without displaying a parking permit, currently valid for that location. The Director may revoke or refuse to issue or renew any parking permit for violation of this section, or any provision of this part.

§ 3.25 Servicing of vehicles.

A person may not wash, polish, change oil, lubricate, or make nonemergency repairs on a privately owned vehicle.

§ 3.26 Speed limit.

The speed limit is 25 miles per hour, unless otherwise posted. A driver of a vehicle may not exceed the speed limit.

§ 3.27 Bicycles.

A person may not operate a bicycle, motorbike, or similar vehicle without a horn or other warning device, and, if the vehicle is operated between dusk and dawn, it must be equipped with an operating headlight, and taillight or reflector.

Subpart C—Facilities and Grounds

§ 3.41 Admission to facilities or grounds.

The enclave is officially open to the public during normal working and visiting hours and for approved public events. The enclave is closed to the public at all other times, and the Director may also officially close all or part of the enclave, or any building, in emergency situations and at other times the Director deems necessary to ensure the orderly conduct of Government business. When all or part of the enclave is closed to the public, admission is restricted to employees and other authorized persons who may be required to display Government credentials or other identification when requested by a police officer and may be required to sign a register. The living quarters and adjacent areas are not open to the public but are open at all times to occupants and their visitors and business invitees, unless otherwise closed by the Director.

§ 3.42 Restricted activities.

(a) *Hobbies and sports.* A person may undertake hobbies and sports only in designated areas or as approved by the Director.

(b) *Pets and other animals.* A person may not bring on the enclave any cat, dog, or other animal except for authorized purposes. This prohibition does not apply to domestic pets at living quarters or to the exercise of these pets under leash or other appropriate restraints. The use of a dog by a handicapped person to assist that person is authorized.

(c) *Photography.* A person may take photographs, films or audiovisuals, for personal or news purposes on the grounds of the enclave or in entrances, lobbies, foyers, corridors, and auditoriums in use for public meetings, except when contrary to security regulations or Department of Health and Human Services policies, or where prohibited by appropriate signs. Photographs and similar activities for advertising or commercial purposes may be taken only with the advance written approval of the Director. A person may take photographs of a patient only with the informed consent of the patient (or the natural or legal guardian) and of the Director of the Warren Grant Magnuson Clinical Center or delegate.

(d) *Intoxicating beverages, narcotics, and other controlled substances.* A person may not possess, sell, consume, or use alcohol or other intoxicating beverages, except in connection with official duties, as part of authorized research, or as otherwise authorized by the Director, or, in the case of possession, consumption or use only, in living quarters. (The sale, consumption, use, or possession of narcotics and other controlled substances is prohibited and shall be governed by the Controlled Substances Act (21 U.S.C. 841-845); driving under the influence of an alcoholic beverage, drug or controlled substance is prohibited and shall be governed by the Maryland *Transportation Code Annotated* section 21-902.)

(e) *Nuisances and disturbances.* The following acts by a person are prohibited: Unwarranted loitering, disorderly conduct (acting in a disorderly manner to the disturbance of the public peace is prohibited and shall be governed by *Maryland Code Annotated,* Article 27, section 122); littering or disposal of rubbish in an unauthorized manner, the creation of any hazard to persons or property; the throwing of articles of any kind from or at a building; the climbing upon any part of a building for other than an authorized purpose; the loud playing of radios or other similar devices; and rollerskating, skateboarding, sledding or similar activities, except in officially designated areas.

(f) *Smoking.* Except as part of an approved medical research protocol, a person may not smoke in any building on the enclave.

§ 3.43 Removal of property.

A person may not remove Federal property from the enclave or any building on the enclave without a property pass, signed by an authorized property custodian, which specifically describes the items to be removed. In an emergency, or when the property custodian is not available, a police officer may approve removal of Federal property if, after consulting with the administrative officer or other appropriate official, the police officer is authorized by the official to do so. Privately-owned property, other than that ordinarily carried on one's person, may be removed only under this property pass procedure, or upon properly establishing ownership of the property to a police officer.

Packages, briefcases, or other containers brought within the enclave are subject to inspection while on, or being removed from, the enclave.

§ 3.44 Solicitation.

It shall be unlawful for a person (other than an employee using authorized bulletin boards), without prior written approval of the Director, to offer or display any article or service for sale within the enclave buildings or grounds; or to display any sign, placard, or other form of advertisement; or to collect private debts; or to solicit business, alms, subscriptions or contributions, except in connection with approved national or local campaigns for funds for welfare, health and other public interest purposes, or solicitation of labor organization membership or dues as authorized under the Civil Service Reform Act of 1978 (Pub. L. 95-454). This provision shall not apply to authorized lessees and their agents and employees with regard to space leased for commercial, cultural, educational, or recreational purposes, under the Public Buildings Cooperative Use Act of 1976 (40 U.S.C. 490(A)(16)).

Subpart D—Penalties

§ 3.61 Penalties.

(a) A person found guilty of violating any provision of the regulations in this part is subject to a fine of not more than $50 or imprisonment of not more than thirty days or both, for each violation (40 U.S.C. 318c).

(b) Penalties for violation of offenses proscribed by Federal statutes (generally codified in title 18 of the United States Code) and Maryland criminal statutes which are made Federal offenses under the Assimilative Crimes Act and are prescribed in the applicable provisions of those statutes.

PART 4—SERVICE OF PROCESS

Sec.
4.1 Suits against the Department and its employees in their official capacities.
4.2 Other process directed to the Department or Secretary.
4.3 Process against Department officials in their individual capacities.
4.4 Acknowledgment of mailed process.
4.5 Effect of regulations.
4.6 Materials related to petitions under the National Vaccine Injury Compensation Program.

AUTHORITY: 5 U.S.C. 301, 42 U.S.C. 300aa-11.

SOURCE: 48 FR 24079, May 31, 1983, unless otherwise noted.

§ 4.1 Suits against the Department and its employees in their official capacities.

Summonses and complaints to be served by mail on the Department of Health and Human Services, the Secretary of Health and Human Services, or other employees of the Department in their official capacities should be sent to the General Counsel, Department of Health and Human Services, 200 Independence Avenue, S.W., Washington, DC 20201.

§ 4.2 Other process directed to the Department or Secretary.

Subpoenas and other process (other than summonses and complaints) that are required to be served on the Department of Health and Human Services or the Secretary of Health and Human Services in his official capacity should be served as follows:

(a) If authorized by law to be served by mail, any mailed process should be sent to the General Counsel, Department of Health and Human Services, 200 Independence, S.W., Washington, DC 20201.

(b) If served by an individual, the process should be delivered to the staff of the correspondence control unit in the Office of the General Counsel, Room 711-E, 200 Independence Avenue, S.W., Washington, DC, or, in the absence of that staff, to any Deputy General Counsel or secretary to any Deputy General Counsel of the Department.

§ 4.3 Process against Department officials in their individual capacities.

Process to be served on Department officials in their individual capacities must be served in compliance with the requirements for service of process on individuals who are not governmental officials. The Office of the General Counsel is authorized but not required to accept process to be served on Departmental officials in their individual capacities if the suit relates to an employee's official duties.

§ 4.4 Acknowledgement of mailed process.

The Department will not provide a receipt or other acknowledgement of process received, except for a return receipt associated with certified mail and, where required, the acknowledgement specified by Rule 4(c)(2)(C) of the Federal Rules of Civil Procedure.

§ 4.5 Effect of regulations.

The regulations in this part are intended solely to identify Department officials who are authorized to accept service of process. Litigants must comply with all requirements pertaining to service of process that are established by statute and court rule even though they are not repeated in these regulations.

§ 4.6 Materials related to petitions under the National Vaccine Injury Compensation Program.

Notwithstanding the provisions of §§ 4.1, 4.2, and 4.3, service of the Secretary's copies of petitions for compensation under the National Vaccine Injury Compensation Program and of related filings, whether by mail or in person, shall be upon the Director, Bureau of Health Professions, 5600 Fishers Lane, Suite 8-05, Rockville, Maryland 20857.

[53 FR 49552, Dec. 8, 1988]

PART 5—FREEDOM OF INFORMATION REGULATIONS

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AUTHORITY: 5 U.S.C. 552, 18 U.S.C. 1905, 31 U.S.C. 9701, 42 U.S.C. 1306(c), E.O. 12600.

SOURCE: 53 FR 47700, Nov. 25, 1988, unless otherwise noted.

Subpart A—Basic Policy

§ 5.1 Purpose.

This part contains the rules that the Department of Health and Human Services (HHS) follows in handling requests for records under the Freedom of Information Act (FOIA). It describes how to make a FOIA request; who can release records and who can decide not to release; how much time it should take to make a determination regarding release; what fees may be charged; what records are available for public inspection; why some records are not released; and your right to appeal and then go to court if we refuse to release records.

§ 5.2 Policy.

As a general policy, HHS follows a balanced approach in administering FOIA. We not only recognize the right of public access to information in the possession of the Department, but also protect the integrity of internal processes. In addition, we recognize the legitimate interests of organizations or persons who have submitted records to the Department or who would otherwise be affected by release of records. For example, we have no discretion to release certain records, such as trade secrets and confidential commercial information, prohibited from release by law. This policy calls for the fullest responsible disclosure consistent with those requirements of administrative necessity and confidentiality which are recognized in the Freedom of Information Act.

§ 5.3 Scope.

These rules apply to all components of the Department. Some units may establish additional rules because of unique program requirements, but such rules must be consistent with these rules and must have the concurrence of the Assistant Secretary for Public Affairs. Existing implementing rules remain in effect to the extent that they are consistent with the new Departmental regulation. If additional rules are issued, they will be published in the FEDERAL REGISTER, and you may get copies from our Freedom of Information Officers.

§ 5.4 Relationship between the FOIA and the Privacy Act of 1974.

(a) *Coverage.* The FOIA and this rule apply to all HHS records. The Privacy Act, 5 U.S.C. 552a, applies to records that are about individuals, but only if the records are in a system of records. "Individuals" and "system of records" are defined in the Privacy Act and in our Privacy Act regulation, Part 5b of this title.

(b) *Requesting your own records.* If you are an individual and request records, then to the extent you are requesting your own records in a system of records, we will handle your request under the Privacy Act and Part 5b. If there is any record that we need not release to you under those provisions, we will also consider your request under the FOIA and this rule, and we will release the record to you if the FOIA requires it.

(c) *Requesting another individual's record.* Whether or not you are an individual, if you request records that are about an individual (other than yourself) and that are in a system of records, we will handle your request under the FOIA and this rule. (However, if our disclosure in response to your request would be permitted by the Privacy Act's disclosure provision, 5 U.S.C. 552a(b), for reasons other than the requirements of the FOIA, and if we decide to make the disclosure, then we will not handle your request under the FOIA and this rule. For example, when we make routine use disclosures pursuant to requests, we do not handle them under the FOIA and this rule. "Routine use" is defined in the Privacy Act and in Part 5b). If we handle your request under the FOIA and this rule and the FOIA does not require releasing the record to you, then the Privacy Act may prohibit the release and remove our discretion to release.

§ 5.5 Definitions.

As used in this part,

"Agency" means any executive department, military department, government corporation, government controlled corporation, or other establishment in the executive branch of the Federal Government, or any independent regulatory agency. Thus, HHS is an agency. A private organization is not an agency even if it is performing work under contract with the Government or is receiving Federal financial assistance. Grantee and contractor records are not subject to the FOIA unless they are in the possession or under the control of HHS or its agents, such as Medicare health insurance carriers and intermediaries.

"Commercial use" means, when referring to a request, that the request is from or on behalf of one who seeks information for a use or purpose that furthers the commercial, trade, or profit interests of the requester or of a person on whose behalf the request is made. Whether a request is for a commercial use depends on the purpose of the request and the use to which the records will be put; the identity of the requester (individual, non-profit corporation, for-profit corporation), on the nature of the records, while in some cases indicative of that purpose or use, is not necessarily determinative. When a request is from a representative of the news media, a purpose or use supporting the requester's news dissemination function is not a commercial use.

"Department" or "HHS" means the Department of Health and Human Services. It includes Medicare health insurance carriers and intermediaries to the extent they are performing functions under agreements entered into under sections 1816 and 1842 of the Social Security Act, 42 U.S.C. 1395h, 1395u.

"Duplication" means the process of making a copy of a record and sending it to the requester, to the extent necessary to respond to the request. Such copies include paper copy, microform, audio-visual materials, and magnetic tapes, cards, and discs.

"Educational institution" means a preschool, elementary or secondary school, institution of undergraduate or graduate higher education, or institution of professional or vocational education, which operates a program of scholarly research.

"Freedom of Information Act" or "FOIA" means section 552 of Title 5, United States Code, as amended.

"Freedom of Information Officer" means an HHS official who has been delegated the authority to release or withhold records and assess, waive, or reduce fees in response to FOIA requests.

"Non-commercial scientific institution" means an institution that is not operated substantially for purposes of furthering its own or someone else's business, trade, or profit interests, and that is operated for purposes of conducting scientific research whose results are not intended to promote any particular product or industry.

"Records" means any handwritten, typed, or printed documents (such as memoranda, books, brochures, studies, writings, drafts, letters, transcripts, and minutes) and documentary material in other forms (such as punchcards; magnetic tapes, cards, or discs; paper tapes; audio or video recordings; maps; photographs; slides; microfilm; and motion pictures). It does not include objects or articles such as exhibits, models, equipment, and duplication machines or audiovisual processing materials. Nor does it include books, magazines, pamphlets, or other reference material in formally organized and officially designated HHS libraries, where such materials are available under the rules of the particular library.

"Representative of the news media" means a person actively gathering information for an entity organized and operated to publish or broadcast news to the public. News media entities include television and radio broadcasters, publishers of periodicals who distribute their products to the general public or who make their products available for purchase or subscription by the general public, and entities that may disseminate news through other media (e.g., electronic dissemination of text). We will treat freelance journalists as representatives of a new media entity if they can show a likelihood of publication through such an entity. A publication contract is such a basis, and the requester's past publication record may show such a basis.

"Request" means asking for records, whether or not you refer specifically to the Freedom of Information Act. Requests from Federal agencies and court orders for documents are not included within this definition. Subpoenas are requests only to the extent provided by Part 2 of this title.

"Review" means, when used in connection with processing records for a commercial use request, examining the records to determine what portions, if any, may be withheld, and any other processing that is necessary to prepare the records for release. It includes only the examining and processing that are done the first time we analyze whether a specific exemption applies to a particular record or portion of a record. It does not include examination done in the appeal stage with respect to an exemption that was applied at the initial request stage. However, if we initially withhold a record under one exemption, and on appeal we determine that that exemption does not apply, then examining the record in the appeal stage for the purpose of determining whether a different exemption applies is included in "review." It does not include the process of researching or resolving general legal or policy issues regarding exemptions.

"Search" means looking for records or portions of records responsive to a request. It includes reading and interpreting a request, and also page-by-page and line-by-line examination to identify responsive portions of a document. However, it does not include line-by-line examination where merely duplicating the entire page would be a less expensive and quicker way to comply with the request.

Subpart B—Obtaining a Record

§ 5.21 How to request records.

(a) *General.* Our policy is to answer all requests, both oral and written, for records. However, in order to have the rights given you by the FOIA and by this regulation (for example, the right to appeal if we deny your request and the right to have our decisions reviewed in court), you must either make your request in writing or make it orally to a Freedom of Information Officer. Freedom of Information Officers and their staffs may put in writing any oral requests they receive directly.

(b) *Addressing requests.* It will help us to handle your request sooner if you address it to the Freedom of Information Officer in the HHS unit that is most likely to have the records you want. (See § 5.31 of this Part for a list of Freedom of Information Officers.) If you cannot determine this, send the request to: HHS Freedom of Information Officer, 645-F, Hubert H. Humphrey Building, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201. Write the words "Freedom of Information Act Request" on the envelope and letter.

(c) *Details in the letter.* You should provide details that will help us identify and find the records you are requesting. If there is insufficient information, we will ask you for more. Include your telephone number(s) to help us reach you if we have questions. If you are not sure how to write your request or what details to include, communicate with a Freedom of Information Officer.

§ 5.22 Requests not handled under the FOIA.

(a) We will not handle your request under the FOIA and this regulation to the extent it asks for records that are currently available, either from HHS or from another part of the Federal Government, under a statute that provides for charging fees for those records. For example, we will not handle your request under the FOIA and this regulation to the extent it asks for detailed earnings statements under the Social Security program, or records currently available from the Government Printing Office of the National Technical Information Service.

(b) We will not handle your request under the FOIA and this regulation to the extent it asks for records that are distributed by an HHS program office as part of its regular program activity, for example, health education brochures distributed by the Public Health Service or public information leaflets distributed by the Social Security Administration.

§ 5.23 Referral of requests outside the Department.

If you request records that were created by, or provided to us by, another Federal agency, and if that agency asserts control over the records, we may refer the records and your request to that agency. We may likewise refer requests for classified records to the agency that classified them. In these cases, the other agency will process and respond to your request, to the extent it concerns those records, under that agency's regulation, and you need not make a separate request to that agency. We will notify you when we refer your request to another agency.

§ 5.24 Responding to your request.

(a) *Retrieving records.* The Department is required to furnish copies of records only when they are in our possession or we can retrieve them from storage. If we have stored the records you want in the National Archives or another storage center, we will retrieve and review them for possible disclosure. However, the Federal Government destroys many old records, so sometimes it is impossible to fill requests. Various laws, regulations, and manuals give the time periods for keeping records before they may be destroyed. For example, there is information about retention of records in the Records Disposal Act of 1944, 44 U.S.C. 3301 through 3314; the Federal Property Management Regulations, 41 CFR 101-11.4; the General Records Schedules of the National Archives and Records Administration; and in the HHS Handbook: *Files Maintenance and Records Disposition.*

(b) *Furnishing records.* The requirement is that we furnish copies only of records that we have or can retrieve. We are not compelled to create new records. For example, we are not required to write a new program so that a computer will print information in the format you prefer. However, if the requested information is maintained in computerized form, but we can, with minimal computer instructions, produce the information on paper, we will do this if it is the only way to respond to a request. Nor are we required to perform research for you.

On the other hand, we may decide to conserve government resources and at the same time supply the records you need by consolidating information from various records rather than copying them all. Moreover, we are required to furnish only one copy of a record and usually impose that limit. If information exists in different forms, we will provide the record in the form that best conserves government resources. For example, if it requires less time and expense to provide a computer record as a paper printout rather than in an electronic medium, we will provide the printout.

Subpart C—Release and Denial of Records

§ 5.31 Designation of authorized officials.

(a) *Freedom of Information Officers.* To provide coordination and consistency in responding to FOIA requests, only Freedom of Information Officers have the authority to release or deny records. These same officials determine fees.

(1) *HHS Freedom of Information Officer.* Only the HHS Freedom of Information Officer may determine whether to release or deny records in any of the following situations:

(i) The records you seek include records addressed to or sent from an official or office of the Office of the Secretary, including its staff offices, or of any Regional Director's Office;

(ii) The records you seek include any records of the Office of Human Development Services, the Family Support Administration, or any organizational unit of HHS not specifically indentified below; or

(iii) The records include records of more than one of the major units identified below (PHS, HCFA, and SSA) either at headquarters or in a Regional Office.

(2) *PHS Freedom of Information Officer.* If the records you seek are exclusively records of the Public Health Service or if the records you seek involve more than one health agency of the Public Health Service, including its records in the regions, only the Deputy Assistant Secretary for Health (Communications), who also is the PHS Freedom of Information Officer, may determine whether to release or deny the records, except as follows:

(i) *CDC and ATSDR Freedom of Information Officer.* If the records you seek are exclusively records of the Centers for Disease Control and/or the Agency for Toxic Substances and Disease Registry, only the Director, Office of Public Affairs, CDC, who also is the CDC and ATSDR Freedom of Information Officer, may determine whether to release or deny the records.

(ii) *FDA Freedom of Information Officer.* If the records you seek are exclusively records of the Food and Drug Administration, only the Associate Commissioner for Public Affairs, FDA, who also is the FDA Freedom of Information Officer, may determine whether to release or deny the records.

(iii) *NIH Freedom of Information Officer.* If the records you seek are exclusively records of the National Institutes of Health, only the Associate Director of Communications, HIH, who also is the NIH Freedom of Information Officer, may determine whether to release or deny the records.

(iv) *HRSA Freedom of Information Officer.* If the records you seek are exclusively records of the Health Resources and Services Administration, only the Associate Administrator for Communications, HRSA, who also is the HRSA Freedom of Information Officer, may determine whether to release or deny the records.

(v) ADAMHA Freedom of Information Officer. If the records you seek are exclusively records of the Alcohol, Drug Abuse and Mental Health Administration, only the Associate Administrator for Communications and Public Affairs, ADAMHA, who is also the ADAMHA Freedom of Information Officer, may determine whether to release or deny the records.

(vi) *IHS Freedom of Information Officer.* If the records you seek are exclusively records of the Indian Health Service, only the Director of Communications, IHS, who also is the IHS Freedom of Information Officer, may determine whether to release or deny the records.

(3) *SSA Freedom of Information Officer.* If the records you seek are exclusively records of the Social Security

Administration, including its records in the regions, only the Director, Office of Public Inquiries, SSA, who also is the SSA Freedom of Information Officer, may determine whether to release or deny the records.

(4) *HCFA Freedom of Information Officer.* If the records you seek are exclusively records of the Health Care Financing Administration, including its records in the regions, only the Director, Office of Public Affairs, HCFA, who also is the HCFA Freedom of Information Officer, may determine whether to release or deny the records.

(b) *Delegations.* Any of the above Freedom of Information Officers may delegate his or her authority to release or deny records and to determine fees. Any such delegation requires the concurrence of the Assistant Secretary for Public Affairs.

(c) *Addresses and telephone numbers.* The addresses and telephone numbers of the Freedom of Information Officers are listed below.

FREEDOM OF INFORMATION OFFICERS

HHS Freedom of Information Officer, Room 645-F, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, *Tel:* (202) 472-7453

SSA Freedom of Information Officer, Room 4-H-8, Annex Building, 6401 Security Boulevard, Baltimore, Maryland 21235, *Tel:* (301) 965-3962

HCFA Freedom of Information Officer, Room 100, Professional Building, Office of Public Affairs, 6660 Security Boulevard, Baltimore, Maryland 21207, *Tel:* (301) 966-5352

PHS Freedom of Information Officer, Room 13-C-24, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, *Tel:* (301) 443-5252

FDA Freedom of Information Officer, HFW-35, Room 12A16, Parklawn Building, 5600 Fishers Land, Rockville, Maryland 20857, *Tel:* (301) 443-1813

NIH Freedom of Information Officer, National Institutes of Health, Building 31, Room 2B39, 9000 Rockville Pike, Bethesda, Maryland 20892, *Tel:* (301) 496-5633

CDC Freedom of Information Officer, Centers for Disease Control, 1600 Clifton Road, NE., Atlanta, Georgia 30333, *Tel:* (404) 329-3286

HRSA Freedom of Information Officer, Room 14-43, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, *Tel:* (301) 443-2086

ADAMHA Freedom of Information Officer, Room 12-C-15, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, *Tel:* (301) 443-3783

IHS Freedom of Information Officer, Room 5-A-39, Parklawn Building, 5600 Fishers Land, Rockville, Maryland 20857, *Tel:* (301) 443-1397.

§ 5.32 Release of records.

(a) *Records previously released.* If we have released a record, or a part of a record, to others in the past, we will ordinarily release it to you also. However, we will not release it to you if a statute forbids this disclosure, and we will not necessarily release it to you if an exemption applies in your situation and did not apply, or applied differently, in the previous situations.

(b) *Unauthorized disclosure.* The principle stated in paragraph (a) of this section, does not apply if the previous release was unauthorized.

(c) *Poor copy.* If we cannot make a legible copy of a record to be released, we do not attempt to reconstruct it. Instead, we furnish the best copy possible and note its poor quality in our reply.

§ 5.33 Denial of requests.

(a) *Information furnished.* All denials are in writing and describe in general terms the material withheld; state the reasons for the denial, including, as applicable, a reference to the specific exemption of the FOIA authorizing the withholding or deletion; explain your right to appeal the decision and identify the official to whom you should send the appeal; and are signed by the person who made the decision to deny all or part of the request.

(b) *Unproductive searches.* We make a diligent search for records to satisfy your request. Nevertheless, we may not be able always to find the records you want using the information you provided, or they may not exist. If we advise you that we have been unable to find the records despite a diligent search, this does not constitute a denial of your request.

§ 5.34 Appeal of denials.

(a) *Right of appeal.* You have the right to appeal a partial or full denial of your FOIA request. To do so, you must put your appeal in writing and send it to the review official identified in the denial letter. You must send your appeal within 30 days from the date you receive that letter or from the date you receive the records released as a partial grant of your request, whichever is later.

(b) *Letter of appeal.* The appeal letter should state reasons why you believe that the FOIA exemption(s) we cited do not apply to the records that you requested, or give reasons why they should be released regardless of whether the exemption(s) apply. Because we have some discretionary authority in deciding whether to release or withhold records, you may strengthen your request by explaining your reasons for wanting the records. However, you are not required to give any explanation.

(c) *Review process.* Before making a decision on an appeal of a denial, the designated review official will consult with the General Counsel to ensure that the rights and interests of all parties affected by the request are protected. Also, the concurrence of the Assistant Secretary for Public Affairs is required in all appeal decisions, including those on fees. When the review official responds to an appeal, that constitutes the Department's final action on the request. If the review official grants your appeal, we will send the records to you promptly or let you inspect them, or else we will explain the reason for any delay and the approximate date you will receive copies or be allowed to inspect the records. If the decision is to deny your appeal, the official will state the reasons for the decision in writing and inform you of the FOIA provision for judicial review.

§ 5.35 Time limits.

(a) *General.* FOIA sets certain time limits for us to decide whether to disclose the records you requested, and to decide appeals. If we fail to meet the deadlines, you may proceed as if we had denied your request or your appeal. We will try diligently to comply with the time limits, but if it appears that processing your request may take longer than we would wish, we will acknowledge your request and tell you its status. Since requests may be misaddressed or misrouted, you should call or write to confirm that we have the request and to learn its status if you have not heard from us in a reasonable time.

(b) *Time allowed.* (1) We will decide whether to release records within 10 working days after your request reaches the appropriate FOI office, as identified in § 5.31 of this part. When we decide to release records, we will actually provide the records, or let you inspect them, as soon as possible after that decision.

(2) We will decide an appeal within 20 working days after the appeal reaches the appropriate review official

(c) *Extension of time limits.* FOI Officers of review officials may extend the time limits in unusual circumstances. Extension at the request stage and at the appeal stage may total up to 10 working days. We will notify you in writing of any extension. "Unusual circumstances" include situations when we:

(1) Search for and collect records from field facilites, archives, or locations other than the office processing the request.

(2) Search for, collect, or examine a great many records in response to a single request.

(3) Consult with another office or agency that has substantial interest in the determination of the request.

(4) Conduct negotiations with submitters and requesters of information to determine the nature and extent of non-disclosable proprietary materials.

Subpart D—Fees

§ 5.41 Fees to be charged—categories of requests.

The paragraphs below state, for each category of request, the type of fees that we will generally charge. However, for each of these categories, the fees may be limited, waived, or reduced for the reasons given in §§ 5.42 through 5.45 or for other reasons.

(a) *Commercial use request.* If your request is for a commercial use, HHS will charge you the costs of search, review, and duplication.

(b) *Educational and scientific institutions and news media.* If you are an educational institution or a non-commercial scientific institution, operated primarily for scholarly or scientific research, or a representative of the news media, and your request is not for a commercial use, HHS will charge you only for the duplication of documents. Also, HHS will not charge you the copying costs for the first 100 pages of duplication.

(c) *Other requesters.* If your request is not the kind described by paragraph (a) or (b) of this section, then HHS will charge you only for the search and the duplication. Also, we will not charge you for the first two hours of search time or for the copying costs of the first 100 pages of duplication.

§ 5.42 Fees to be charged—general provisions.

(a) We may charge search fees even if the records we find are exempt from disclosure, or even if we do not find any records at all.

(b) If we are not charging you for the first two hours of search time, under § 5.41(c), and those two hours are spent on a computer search, then the two free hours are the first two hours of the operator's own operation. If the operator spends less than two hours on the search, we well reduce the total search fees by the average hourly rate for the operator's time, multipled by two.

(c) If we are not charging you for the first 100 pages of duplication, under § 5.41 (b) or (c), then those 100 pages are the first 100 pages of photocopies of standard size pages, or the first 100 pages of computer printout. If we cannot use this method to calculate the fee reduction, then we will reduce your total duplication fee by the normal charge for photocopying a standard size page, multiplied by 100.

(d) We will not charge you any fee at all if the costs of routine collection and processing of the fee are likely to equal or exceed the amount of the fee. As of May 1987, such costs among the units HHS ranged between $6.00 and $12.50.

(e) If we determine that you (acting either alone or together with others) are breaking down a single request into a series of requests in order to avoid (or reduce) the fees charged, we may aggregate all these requests for purposes of calculating the fees charged.

(f) We will charge interest on unpaid bills beginning on the 31st day following the day the bill was sent. We will use the provisions of Part 30 of this Title in assessing interest, administrative costs, and penalties and in taking actions to encourage payment.

(g) This subpart does not apply to requests for Social Security program records on Social Security number holders, wage earners, employers, and claimants, where the requests are governed by section 1106 of the Social Security Act, 42 U.S.C. 1306(c), and by 20 CFR 442.441.

§ 5.43 Fee schedule.

HHS charges the following fees:

(a) Manual searching for or reviewing of records—when the search or review is performed by employees at grade GS-1 through GS-8, an hourly rate based on the salary of a GS-5, step 7, employee; when done by a GS-9 through GS-14, an hourly rate based on the salary of a GS-12, step 4, employee; and when done by a GS-15 or above, an hourly rate based on the salary of a GS-15, step 7, employee. In each case, the hourly rate will be computed by taking the current hourly rate for the specified grade and step, adding 16% of that rate to cover benefits, and rounding to the nearest whole dollar. As of November 25, 1988, these rates were $10, $20, and $37 respectively. When a search involves employees at more than one of these levels, we will charge the rate appropriate for each.

(b) Computer searching and printing—the actual cost of operating the computer plus charges for the time spent by the operator, at the rates given in paragraph (a) of this section.

(c) Photocopying standard size pages—$0.10 per page. FOI Officers may charge lower fees for particular documents where—

(1) The document has already been printed in large numbers,

(2) The program office determines that using existing stock to answer

this request, and any other anticipated FOI requests, will not interfere with program requirements, and

(3) The FOI Officer determines that the lower fee is adequate to recover the prorated share of the original printing costs.

(d) Photocopying odd-size documents (such as punchcards or blueprints), or reproducing other records (such as tapes)—the actual costs of operating the machine, plus the actual cost of the materials used, plus charges for the time spent by the operator, at the rates given in paragraph (a) of this section.

(e) Certifying that records are true copies. This service is not required by the FOIA. If we agree to provide it, we will charge $10 per certification.

(f) Sending records by express mail, certified mail, or other special methods. This service is not required by the FOIA. If we agree to provide it, we will charge our actual costs.

(g) Performing any other special service that you request and we agree to—actual costs of operating any machinery, plus actual cost of any materials used, plus charges for the time of our employees, at the rates given in paragraph (a) of this section.

§ 5.44 Procedures for assessing and collecting fees.

(a) *Agreement to pay.* We generally assume that when you request records you are willing to pay the fees we charge for services associated with your request. You may specify a limit on the amount you are willing to spend. We will notify you if it appears that the fees will exceed the limit and ask whether you nevertheless want us to proceed with the search.

(b) *Advance payment.* If you have failed to pay previous bills in a timely fashion, or if our initial review of your request indicates that we will charge you fees exceeding $250, we will require you to pay your past due fees and/or the estimated fees, or a deposit, before we start searching for the records you want. If so, we will let you know promptly upon receiving your request. In such cases, the administrative time limits prescribed in § 5.35 of the part (i.e., ten working days from receipt of initial requests and 20 working days from receipt of appeals from initial denials, plus permissible extensions of these time limits) will begin only after we come to an agreement with you over payment of fees, or decide that fee waiver or reduction is appropriate.

(c) *Billing and payment.* We will normally require you to pay all fees before we furnish the records to you. We may, at our discretion, send you a bill along with or following the furnishing of the records. For example, we may do this if you have a history of prompt payment. We may also, at our discretion, aggregate the charges for certain time periods in order to avoid sending numerous small bills to frequent requesters, or to businesses or agents representing requesters. For example, we might send a bill to such a requester once a month. Fees should be paid in accordance with the instructions furnished by the person who responds to your requests.

§ 5.45 Waiver or reduction of fees.

(a) *Standard.* We will waive or reduce the fees we would otherwise charge if disclosure of the information meets both of the following tests:

(1) It is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government, and

(2) It is not primarily in the commercial interest of the requester.

These two tests are explained in paragraphs (b) and (c) of this section.

(b) *Public interest.* The disclosure passes the first test only if it furthers the specific public interest of being likely to contribute significantly to public understanding of government operations or activities, regardless of any other public interest it may further. In analyzing this question, we will consider the following factors.

(1) How, if at all, do the records to be disclosed pertain to the operations or activities of the Federal Government?

(2) Would disclosure of the records reveal any meaningful information about government operations or activities? Can one learn from these records

anything about such operations that is not already public knowledge?

(3) Will the disclosure advance the understanding of the general public as distinguished from a narrow segment of interested persons? Under this factor we may consider whether the requester is in a position to contribute to public understanding. For example, we may consider whether the requester has such knowledge or expertise as may be necessary to understand the information, and whether the requester's intended use of the information would be likely to disseminate the information among the public. An unsupported claim to be doing research for a book or article does not demonstrate that likelihood, while such a claim by a representative of the news media is better evidence.

(4) Will the contribution to public understanding be a significant one? Will the public's understanding of the government's operations be substantially greater as a result of the disclosure?

(c) *Not primarily in the requester's commercial interest.* If the disclosure passes the test of furthering the specific public interest described in paragraph (b) of this section, we will determine whether it also furthers the requester's commercial interest and, if so, whether this effect outweighs the advancement of that public interest. In applying this second test, we will consider the following factors:

(1) Would the disclosure further a commercial interest of the requester, or of someone on whose behalf the requester is acting? "Commercial interests" include interests relating to business, trade, and profit. Not only profit-making corporations have commercial interests—so do nonprofit corporations, individuals, unions, and other associations. The interest of a representative of the news media in using the information for news dissemination purposes will not be considered a commercial interest.

(2) If disclosure would further a commercial interest of the requester, would that effect outweigh the advancement of the public interest defined in paragraph (b) of this section? Which effect is primary?

(d) *Deciding between waiver and reduction.* If the disclosure passes both tests, we will normally waive fees. However, in some cases we may decide only to reduce the fees. For example, we may do this when disclosure of some but not all of the requested records passes the tests.

(e) *Procedure for requesting a waiver or reduction.* You must make your request for a waiver or reduction at the same time you make your request for records. You should explain why you believe a waiver or reduction is proper under the analysis in paragraphs (a) through (d) of this section. Only FOI Officers may make the decision whether to waive, or reduce, the fees. If we do not completely grant your request for a waiver or reduction, the denial letter will designate a review official. You may appeal the denial to that official. In your appeal letter, you should discuss whatever reasons are given in our denial letter. The process prescribed in § 5.34(c) of this part will also apply to these appeals.

Subpart E—Records Available for Public Inspection

§ 5.51 Records available.

(a) *Records of general interest.* We will make the following records of general interest available for your inspection and copying. Before releasing them, however, we may delete the names of people, or information that would identify them, if release would invade their personal privacy to a clearly unwarranted degree. (See § 5.67 of this part.)

(1) Orders and final opinions, including concurring and dissenting opinions in adjudications, such as Letters of Finding issued by the Office for Civil Rights in civil rights complaints, and Social Security Rulings. (See § 5.66 of this part for availability of internal memoranda, including attorney opinions and advice.)

(2) Statements of policy and interpretations that we have adopted but have not published in the FEDERAL REGISTER.

(3) Administrative staff manuals and instructions to staff that affect the public. (We will not make available,

however, manuals or instructions that reveal investigative or audit procedures as described in §§ 5.63 and 5.68 of this part.)

(b) *Other records.* In addition to such records as those described in paragraph (a) of this section, we will make available to any person a copy of all other agency records, unless we determine that such records should be withheld from disclosure under subsection (b) of the Act and Subpart F of this regulation.

§ 5.52 Indexes of records.

(a) *Inspection and copying.* We will maintain and provide for your inspection and copying current indexes of the records described in § 5.51(a). We will also publish and distribute copies of the indexes unless we announce in the FEDERAL REGISTER that it is unnecessary or impracticable to do so. For assistance in locating indexes maintained in the Department, you may contact the HHS Freedom of Information Officer at the address and telephone number in § 5.31(c).

(b) *Record citation as precedent.* We will not use or cite any record described in § 5.51(a) as a precedent for an action against a person unless we have indexed the record and published it or made it available, or unless the person has timely notice of the record.

Subpart F—Reasons for Withholding Some Records

§ 5.61 General.

Section 552(b) of the Freedom of Information Act contains nine exemptions to the mandatory disclosure of records. We describe these exemptions below and explain how this Department applies them to disclosure determinations. (In some cases more than one exemption may apply to the same document.) Information obtained by the Department from any individual or organization, furnished in reliance on a provision for confidentiality authorized by applicable statute or regulation, will not be disclosed, to the extent it can be withheld under one of these exemptions. This section does not itself authorize the giving of any pledge of confidentiality by any officer or employee of the Department.

§ 5.62 Exemption one: National defense and foreign policy.

We are not required to release records that, as provided by FOIA, are "(a) specifically authorized under criteria established by an Executive Order to be kept secret in the interest of national defense or foreign policy and (b) are in fact properly classified pursuant to such Executive Order." Executive Order No. 12356 (1982) provides for such classification. When the release of certain records may adversely affect U.S. relations with foreign countries, we usually consult with officials of those countries or officials of the Department of State. Also, we may on occasion have in our possession records classified by some other agency. We may refer your request for such records to the agency that classified them and notify you that we have done so, as explained in § 5.23.

§ 5.63 Exemption two: Internal personnel rules and practices.

We are not required to release records that are "related solely to the internal personnel rules and practices of an agency." Under this exemption, we may withhold routine internal agency practices and procedures. For example, we may withhold guard schedules and rules governing parking facilities or lunch periods. Also under this exemption, we may withhold internal records whose release would help some persons circumvent the law or agency regulations. For example, we ordinarily do not disclose manuals that instruct our investigators or auditors how to investigate possible violations of law, to the extent that this release would help some persons circumvent the law.

§ 5.64 Exemption three: Records exempted by other statutes.

We are not required to release records if another statute specifically allows us to withhold them. We may use another statute to justify withholding only if it absolutely prohibits disclosure or if it sets forth criteria to guide our decision on releasing or identifies particular types of material to be withheld.

§ 5.65 Exemption four: Trade secrets and confidential commercial or financial information.

We will withhold trade secrets and commercial or financial information that is obtained from a person and is privileged or confidential.

(a) *Trade secrets.* A trade secret is a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.

(b) *Commercial or financial information.* We will not disclose records whose information is "commercial or financial," is obtained from a person, and is "privileged or confidential."

(1) Information is "commercial or financial" if it relates to businesses, commerce, trade, employment, profits, or finances (including personal finances). We interpret this category broadly.

(2) Information is "obtained from a person" if HHS or another agency has obtained it from someone outside the Federal Government or from someone within the Government who has a commercial or financial interest in the information. "Person" includes an individual, partnership, corporation, association, state or foreign government, or other organization. Information is not "obtained from a person" if it is generated by HHS or another federal agency. However, information is "obtained from a person" if it is provided by someone, including but not limited to an agency employee, who retains a commercial or financial interest in the information.

(3) Information is "privileged" if it would ordinarily be protected from disclosure in civil discovery by a recognized evidentiary privilege, such as the attorney-client privilege or the work product privilege. Information may be privileged for this purpose under a privilege belonging to a person outside the government, unless the providing of the information to the government rendered the information no longer protectable in civil discovery.

(4) Information is "confidential" if it meets one of the following tests:

(i) Disclosure may impair the government's ability to obtain necessary information in the future;

(ii) Disclosure would substantially harm the competitive position of the person who submitted the information;

(iii) Disclosure would impair other government interests, such as program effectiveness and compliance; or

(iv) Disclosure would impair other private interests, such as an interest in controlling availability of intrinsically valuable records, which are sold in the market by their owner.

The following questions may be relevant in analyzing whether a record meets one of more of the above tests: Is the information of a type customarily held in strict confidence and not disclosed to the public by the person to whom it belongs? What is the general custom or usage with respect to such information in the relevant occupation or business? How many, and what types of, individuals have access to the information? What kind and degree of financial injury can be expected if the information is disclosed?

(c) *Designation of certain confidential information.* A person who submits records to the government may designate part or all of the information in such records as exempt from disclosure under Exemption 4 of the FOIA. The person may make this designation either at the time the records are submitted to the government or within a reasonable time thereafter. The designation must be in writing. Where a legend is required by a request for proposals or request for quotations, pursuant to 48 CFR 352.215-12, then that legend is necessary for this purpose. Any such designation will expire ten years after the records were submitted to the government.

(d) *Predisclosure notification.* The procedures in this paragraph apply to records on which the submitter has designated information as provided in paragraph (c) of this section. They also apply to records that were submitted to the government where we have substantial reason to believe that information in the records could reasonably be considered exempt under Exemption 4. Certain exceptions to these procedures are stated in paragraph (e) of this section.

(1) When we receive a request for such records, and we determine that we may be required to disclose them, we will make reasonable efforts to notify the submitter about these facts. The notice will include a copy of the request, and it will inform the submitter about the procedures and time limits for submission and consideration of objections to disclosure. If we must notify a large number of submitters, we may do this by posting or publishing a notice in a place where the submitters are reasonably likely to become aware of it.

(2) The submitter has five working days from receipt of the notice to object to disclosure of any part of the records and to state all bases for its objections.

(3) We will give consideration to all bases that have been timely stated by the submitter. If we decide to disclose the records, we will notify the submitter in writing. This notice will briefly explain why we did not sustain its objections. We will include with the notice a copy of the records about which the submitter objected, as we propose to disclose them. The notice will state that we intend to disclose the records five working days after the submitter receives the notice unless we are ordered by a United States District Court not to release them.

(4) When a requester files suit under the FOIA to obtain records covered by this paragraph, we will promptly notify the submitter.

(5) Whenever we send a notice to a submitter under paragraph (d)(1) of this section, we will notify the requester that we are giving the submitter a notice and an opportunity to object. Whenever we send a notice to a submitter under paragraph (d)(3) of this section, we will notify the requester of this fact.

(e) *Exceptions to predisclosure notification.* The notice requirements in paragraph (d) of this section do not apply in the following situations:

(1) We decided not to disclose the records;

(2) The information has previously been published or made generally available;

(3) Disclosure is required by a regulation, issued after notice and opportunity for public comment, that specifies narrow categories of records that are to be disclosed under the FOIA, but in this case a submitter may still designate records as described in paragraph (c) of this section, and in exceptional cases, we may, at our discretion, follow the notice procedures in paragraph (d) of this section; or

(5) The designation appears to be obviously frivolous, but in this case we will still give the submitter the written notice required by paragraph (d)(3) of this section (although this notice need not explain our decision or include a copy of the records), and we will notify the requester as described in paragraph (d)(5) of this section.

§ 5.66 Exemption five: Internal memoranda.

This exemption covers internal government communications and notes that fall within a generally recognized evidentiary privilege. Internal government communications include an agency's communications with an outside consultant or other outside person, with a court, or with Congress, when those communications are for a purpose similar to the purpose of privileged intra-agency communications. Some of the most-commonly applicable privileges are described in the following paragraphs.

(a) *Deliberative process privilege.* This privilege protects predecisional deliberative communications. A communication is protected under this privilege if it was made before a final decision was reached on some question of policy and if it expressed recommendations or opinions on that question. The purpose of the privilege is to prevent injury to the quality of the agency decisionmaking process by encouraging open and frank internal policy discussions, by avoiding premature disclosure of policies not yet adopted, and by avoiding the public confusion that might result from disclosing reasons that were not in fact the ultimate grounds for an agency's decision. Purely factual material in a deliberative document is within this privilege only if it is inextricably intertwined with the deliberative portions so that it cannot reasonably be segregated, if it would reveal the nature of the deliberative portions, or if its disclosure would in some other way make possible an intrusion into the decision-making process. We will release purely factual material in a deliberative document unless that material is otherwise exempt. The privilege continues to protect predecisional documents even after a decision is made.

(b) *Attorney work product privilege.* This privilege protects documents prepared by or for an agency, or by or for its representative (typically, HHS attorneys) in anticipation of litigation or for trial. It includes documents prepared for purposes of administrative adjudications as well as court litigation. It includes documents prepared by program offices as well as by attorneys. It includes factual material in such documents as well as material revealing opinions and tactics. Finally, the privilege continues to protect the documents even after the litigation is closed.

(c) *Attorney-client communication privilege.* This privilege protects confidential communications between a lawyer and an employee or agent of the government where there is an attorney-client relationship between them (typically, where the lawyer is acting as attorney for the agency and the employee is communicating on behalf of the agency) and where the employee has communicated information to the attorney in confidence in order to obtain legal advice or assistance.

§ 5.67 Exemption six: Clearly unwarranted invasion of personal privacy.

(a) *Documents affected.* We may withhold records about individuals if disclosure would constitute a clearly unwarranted invasion of their personal privacy.

(b) *Balancing test.* In deciding whether to release records to you that contain personal or private information about someone else, we weigh the foreseeable harm of invading that person's privacy against the public benefit that would result from the release. If you were seeking information for a purely commercial venture, for example, we might not think that disclosure would primarily benefit the public and we would deny your request. On the other hand, we would be more inclined to release information if you were working on a research project that gave promise of providing valuable information to a wide audience. However, in our evaluation of requests for records we attempt to guard against the release of information that might involve a violation of personal privacy because of a requester being able to "read between the lines" or piece together items that would constitute information that normally would be exempt from mandatory disclosure under Exemption Six.

(c) *Examples.* Some of the information that we frequently withhold under Exemption Six is: Home addresses, ages, and minority group status of our employees or former employees; social security numbers; medical information about individuals participating in clinical research studies; names and addresses of individual beneficiaries of our programs, or benefits such individuals receive; earning records, claim files, and other personal information maintained by the Social Security Administration, the Public Health Service, and the Health Care Financing Administration.

§ 5.68 Exemption seven: Law enforcement.

We are not required to disclose information or records that the government has compiled for law enforcement purposes. The records may apply to actual or potential violations of either criminal or civil laws or regulations. We can withhold these records only to the extent that releasing them would cause harm in at least one of the following situations:

(a) *Enforcement proceedings.* We may withhold information whose release could reasonably be expected to interfere with prospective or ongoing law enforcement proceedings. Investigations of fraud and mismanagement, employee misconduct, and civil rights violations may fall into this category. In certain cases—such as when a fraud investigation is likely—we may refuse to confirm or deny the existence of records that relate to the violations in order not to disclose that an investigation is in progress, or may be conducted.

(b) *Fair trial or impartial adjudication.* We may withhold records whose release would deprive a person of a fair trial or an impartial adjudication because of prejudicial publicity.

(c) *Personal privacy.* We are careful not to disclose information that could reasonably be expected to constitute an unwarranted invasion of personal privacy. When a name surfaces in an investigation, that person is likely to be vulnerable to innuendo, rumor, harassment, and retaliation.

(d) *Confidential sources and information.* We may withhold records whose release could reasonably be expected to disclose the identity of a confidential source of information. A confidential source may be an individual; a state, local, or foreign government agency; or any private organization. The exemption applies whether the source provides information under an express promise of confidentiality or under circumstances from which such an assurance could be reasonably inferred. Also, where the record, or information in it, has been compiled by a criminal law enforcement authority conducting a criminal investigation, or by an agency conducting a lawful national security investigation, the exemption also protects all information supplied by a confidential source. Also protected from mandatory disclosure is any information which, if disclosed, could reasonably be expected to jeopardize the system of confidentiality that assures a flow of information from sources to investigatory agencies.

(e) *Techniques and procedures.* We may withhold records reflecting special techniques or procedures of investigation or prosecution, not otherwise generally known to the public. In some cases, it is not possible to describe even in general terms those techniques without disclosing the very material to be withheld. We may also withhold records whose release would disclose guidelines for law enforcement investigations or prosecutions if this disclosure could reasonably be expected to create a risk that someone could circumvent requirements of law or of regulation.

(f) *Life and physical safety.* We may withhold records whose disclosure could reasonably be expected to endanger the life or physical safety of any individual. This protection extends to threats and harassment as well as to physical violence.

§ 5.69 Exemptions 8 and 9: Records on financial institutions; records on wells.

Exemption eight permits us to withhold records about regulation or supervision of financial institutions. Exemption nine permits the withholding of geological and geophysical information and data, including maps, concerning wells.

PART 5a—[RESERVED]

PART 5b—PRIVACY ACT REGULATIONS

Sec.
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5b.7 Procedures for correction or amendment of records.
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Appendix A—Employee Standards of Conduct
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Appendix C—Delegations of Authority [Reserved]

Authority: 5 U.S.C. 301, 5 U.S.C. 552a.

Source: 40 FR 47409, Oct. 8, 1975, unless otherwise noted.

§ 5b.1 Definitions.

As used in this part:

(a) "Access" means availability of a record to a subject individual.

(b) "Agency" means the Department of Health and Human Services.

(c) "Department" means the Department of Health and Human Services.

(d) "Disclosure" means the availability or release of a record to anyone other than the subject individual.

(e) "Individual" means a living person who is a citizen of the United States or an alien lawfully admitted for permanent residence. It does not include persons such as sole proprietorships, partnerships, or corporations. A business firm which is identified by the name of one or more persons is not an individual within the meaning of this part.

(f) "Maintain" means to maintain, collect, use, or disseminate when used in connection with the term "record"; and, to have control over or responsibility for a system of records when used in connection with the term "system of records."

(g) "Notification" means communication to an individual whether he is a subject individual.

(h) "Record" means any item, collection, or grouping of information about an individual that is maintained by the Department, including but not limited to the individual's education, financial transactions, medical history, and criminal or employment history and that contains his name, or an identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or a photograph. When used in this part, record means only a record which is in a system of records.

(i) "Responsible Department official" means that officer who is listed in a notice of a system of records as the system manager for a given system of records or another individual listed in the notice of a system of records to whom requests may be made, or the designee of either such officer or individual.

(j) "Routine use" means the disclosure of a record outside the Department, without the consent of the subject individual, for a purpose which is compatible with the purpose for which the record was collected. It includes disclosures required to be made by statute other than the Freedom of Information Act, 5 U.S.C. 552. It does not include disclosures which are permitted to be made without the consent of the subject individual which are not compatible with the purpose for which it was collected such as disclosures to the Bureau of the Census, the General Accounting Office, or to Congress.

(k) "Secretary" means the Secretary of Health and Human Services, or his designee.

(l) "Statistical record" means a record maintained for statistical research or reporting purposes only and not maintained to make determinations about a particular subject individual.

(m) "Subject individual" means that individual to whom a record pertains.

(n) "System of records" means any group of records under the control of the Department from which a record is retrieved by personal identifier such as the name of the individual, number, symbol or other unique retriever assigned to the individual. Single records or groups of records which are not retrieved by a personal identifier are not part of a system of records. Papers maintained by individual employees of the Department which are prepared, maintained, or discarded at the discretion of the employee and which are not subject to the Federal Records Act, 44 U.S.C. 2901, are not part of a system of records; *Provided*, That such personal papers are not used by the employee or the Department to determine any rights, benefits, or privileges of individuals.

§ 5b.2 Purpose and scope.

(a) This part implements section 3 of the Privacy Act of 1974, 5 U.S.C. 552a (hereinafter referred to as the Act), by establishing agency policies and procedures for the maintenance of records. This part also establishes agency policies and procedures under which a subject individual may be given notification of or access to a record pertaining to him and policies and procedures under which a subject individual may have his record corrected or amended if he believes that his record is not accurate, timely, complete, or relevant or necessary to accomplish a Department function.

(b) All components of the Department are governed by the provisions of this part. Also governed by the provisions of this part are:

(1) Certain non-Federal entities which operate as agents of the Department for purposes of carrying out Federal functions, such as intermediaries and carriers performing functions under contracts and agreements entered into pursuant to sections 1816 and 1842 of the Social Security Act, 42 U.S.C. 1395h and 1395u.

(2) Advisory committees and councils within the meaning of the Federal Advisory Committee Act which provide advice to (i) any official or component of the Department or (ii) the President and for which the Department has been delegated responsibility for providing services.

(c) Employees of the Department governed by this part include all regular and special government employees of the Department; members of the Public Health Service Commissioned Corps; experts and consultants whose temporary (not in excess of 1 year) or intermittent services have been procured by the Department by contract pursuant to 3109 of Title 5, United States Code; volunteers where acceptance of their services are authorized by law; those individuals performing gratuitous services as permitted under conditions prescribed by the Civil Service Commission; and, participants in work-study or training programs.

(d) Where other statutes mandate procedures which are inconsistent with the procedures set forth in this part, components of the Department may issue supplementary regulations containing procedures necessary to comply with such statutes. In addition, components of the Department may supplement by regulation the policies and procedures set forth in this part to meet particular needs of the programs administered by such components.

(e) This part does not:

(1) Make available to a subject individual records which are not retrieved by that individual's name or other personal identifier.

(2) Make available to the general public records which are retrieved by a subject individual's name or other personal identifier or make available to the general public records which would otherwise not be available to the general public under the Freedom of Information Act, 5 U.S.C. 552, and Part 5 of this title.

(3) Govern the maintenance or disclosure of, notification of or access to, records in the possession of the Department which are subject to regulations of another agency, such as personnel records subject to the regulations of the Civil Service Commission.

(4) Apply to grantees, including State and local governments or subdivisions thereof, administering federally funded programs.

(5) Make available records compiled by the Department in reasonable anticipation of court litigation or formal administrative proceedings. The availability of such records to the general public or to any subject individual or party to such litigation or proceedings shall be governed by applicable constitutional principles, rules of discovery, and applicable regulations of the Department and any of its components.

§ 5b.3 Policy.

It is the policy of the Department to protect the privacy of individuals to the fullest extent possible while nonetheless permitting the exchange of records required to fulfill the administrative and program responsibilities of the Department, and responsibilities of the Department for disclosing records which the general public is entitled to have under the Freedom of Information Act, 5 U.S.C. 552, and Part 5 of this title.

§ 5b.4 Maintenance of records.

(a) No record will be maintained by the Department unless:

(1) It is relevant and necessary to accomplish a Department function required to be accomplished by statute or Executive Order;

(2) It is acquired to the greatest extent practicable from the subject individual when maintenance of the record may result in a determination about the subject individual's rights, benefits or privileges under Federal programs;

(3) The individual providing the record is informed of the authority for providing the record (including whether the providing of the record is mandatory or voluntary, the principal purpose for maintaining the record, the routine uses for the record, what effect his refusal to provide the record may have on him), and if the record is not required by statute or Executive Order to be provided by the individual, he agrees to provide the record.

(b) No record will be maintained by the Department which describes how an individual exercises rights guaranteed by the First Amendment unless expressly authorized (1) by statute, or (2) by the subject individual, or (3) unless pertinent to and within the scope of an authorized law enforcement activity.

§ 5b.5 Notification of or access to records.

(a) *Times, places, and manner of requesting notification of or access to a record.* (1) Subject to the provisions governing medical records in § 5b.6 of this part, any individual may request notification of a record. He may at the same time request access to any record pertaining to him. An individual may be accompanied by another individual of his choice when he requests access to a record in person; *Provided,* That he affirmatively authorizes the presence of such other individual during any discussion of a record to which access is requested.

(2) An individual making a request for notification of or access to a record shall address his request to the responsible Department official and shall verify his identity when required in accordance with paragraph (b)(2) of this section. At the time the request is made, the individual shall specify which systems of records he wishes to have searched and the records to which he wishes to have access. He may also request that copies be made of all or any such records. An individual shall also provide the responsible Department official with sufficient particulars to enable such official to distinguish between records on subject individuals with the same name. The necessary particulars are set forth in the notices of systems of records.

(3) An individual who makes a request in person may leave with any responsible Department official a request for notification of or access to a record under the control of another responsible Department official; *Provided,* That the request is addressed in writing to the appropriate responsible Department official.

(b) *Verification of identity*—(1) *When required.* Unless an individual, who is making a request for notification of or access to a record in person, is personally known to the responsible Department official, he shall be required to verify his identity in accordance with paragraph (b)(2) of this section if:

(i) He makes a request for notification of a record and the responsible Department official determines that the mere disclosure of the existence of the record would be a clearly unwarranted invasion of privacy if disclosed to someone other than the subject individual; or,

(ii) He makes a request for access to a record which is not required to be disclosed to the general public under the Freedom of Information Act, 5 U.S.C. 552, and Part 5 of this title.

(2) *Manner of verifying identity.* (i) An individual who makes a request in person shall provide to the responsible Department official at least one piece of tangible identification such as a driver's license, passport, alien or voter registration card, or union card to verify his identity. If an individual does not have identification papers to verify his identity, he shall certify in writing that he is the individual who he claims to be and that he understands that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act subject to a $5,000 fine.

(ii) Except as provided in paragraph (b)(2)(v) of this section, an individual who does not make a request in person shall submit a notarized request to the responsible Department official to verify his identity or shall certify in his request that he is the individual who he claims to be and that he understands that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act subject to a $5,000 fine.

(iii) An individual who makes a request on behalf of a minor or legal incompetent as authorized under § 5b.10 of this part shall verify his relationship to the minor or legal incompetent, in addition to verifying his own identity, by providing a copy of the minor's birth certificate, a court order, or other competent evidence of guardianship to the responsible Department official; *except that*, an individual is not required to verify his relationship to the minor or legal incompetent when he is not required to verify his own identity or when evidence of his relationship to the minor or legal incompetent has been previously given to the responsible Department official.

(iv) An individual shall further verify his identity if he is requesting notification of or access to sensitive records such as medical records. Any further verification shall parallel the record to which notification or access is being sought. Such further verification may include such particulars as the individual's years of attendance at a particular educational institution, rank attained in the uniformed services, date or place of birth, names of parents, an occupation or the specific times the individual received medical treatment.

(v) An individual who makes a request by telephone shall verify his identity by providing to the responsible Department official identifying particulars which parallel the record to which notification or access is being sought. If the responsible Department official determines that the particulars provided by telephone are insufficient, the requester will be required to submit the request in writing or in person. Telephone requests will not be accepted where an individual is requesting notification of or access to sensitive records such as medical records.

(c) *Granting notification of or access to a record.* (1) Subject to the provisions governing medical records in § 5b.6 of this part and the provisions governing exempt systems in § 5b.11 of this part, a responsible Department official, who receives a request for notification of or access to a record and, if required, verification of an individual's identity, will review the request and grant notification or access to a record, if the individual requesting access to the record is the subject individual.

(2) If the responsible Department official determines that there will be a delay in responding to a request because of the number of requests being processed, a breakdown of equipment, shortage of personnel, storage of records in other locations, etc., he will so inform the individual and indicate when notification or access will be granted.

(3) Prior to granting notification of or access to a record, the responsible Department official may at his discretion require an individual making a request in person to reduce his request to writing if the individual has not already done so at the time the request is made.

§ 5b.6 Special procedures for notification of or access to medical records.

(a) *General.* An individual in general has a right to notification of or access to his medical records, including psychological records, as well as to other records pertaining to him maintained by the Department. This section sets forth special procedures as permitted by the Act for notification of or access to medical records, including a special procedure for notification of or access to medical records of minors. The special procedures set forth in paragraph (b) of this section may not be suitable for use by every component of the Department. Therefore, components may follow the paragraph (b) procedure for notification of or access to medical records, or may issue regulations establishing special procedures for such purposes. The special procedure set forth in paragraph (c) of this section relating to medical records of minors is mandatory.

(b) *Medical records procedures*—(1) *Notification of or access to medical records.* (i) Any individual may request notification of or access to a medical record pertaining to him. Unless the individual is a parent or guardian requesting notification of or access to a minor's medical record, an individual shall make a request for a medical record in accordance with this section and the procedures in § 5b.5 of this part.

(ii) An individual who requests notification of or access to a medical record shall, at the time the request is made, designate a representative in writing. The representative may be a physician, other health professional, or other responsible individual, who would be willing to review the record and inform the subject individual of its contents at the representative's discretion.

(2) *Utilization of the designated representative.* A subject individual will be granted direct access to a medical record if the responsible official determines that direct access is not likely to have an adverse effect on the subject individual. If the responsible Department official believes that he is not qualified to determine, or if he does determine, that direct access to the subject individual is likely to have an adverse effect on the subject individual, the record will be sent to the designated representative. The subject individual will be informed in writing that the record has been sent.

(c) *Medical records of minors*—(1) *Requests by minors; notification of or access to medical records to minors.* A minor may request notification of or access to a medical record pertaining to him in accordance with paragraph (b) of this section.

(2) *Requests on a minor's behalf; notification of or access to medical records to an individual on a minor's behalf.* (i) In order to protect the privacy of a minor, a parent or guardian, authorized to act on a minor's behalf as provided in § 5b.10 of this part, who makes a request for notification of or access to a minor's medical record will not be given direct notification of or access to such record.

(ii) A parent or guardian shall make all requests for notification of or access to a minor's medical record in accordance with this paragraph and the procedures in § 5b.5 of this part. A parent or guardian shall at the time he makes a request designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent.

(iii) Where a medical record on the minor exists, it will be sent to the physician or health professional designated by the parent or guardian in all cases. If disclosure of the record would constitute an invasion of the minor's privacy, that fact will be brought to the attention of the physician or health professional to whom the record is sent. The physician or health professional will be asked to consider the effect that disclosure of the record to the parent or guardian would have on the minor in determining whether the minor's medical record should be made available to the parent or guardian. Response to the parent or guardian making the request will be made in substantially the following form:

We have completed processing your request for notification of or access to ———
———'s
(Name of minor)
medical records. Please be informed that if any medical record were found pertaining to that individual, they have not been sent to your designated physician or health professional.

In each case where a minor's medical record is sent to a physician or health professional, reasonable efforts will be made to so inform the minor.

§ 5b.7 Procedures for correction or amendment of records.

(a) Any subject individual may request that his record be corrected or amended if he believes that the record is not accurate, timely, complete, or relevant or necessary to accomplish a Department function. A subject individual making a request to amend or correct his record shall address his request to the responsible Department official in writing; *except that,* the request need not be in writing if the subject individual makes his request in person and the responsible Department official corrects or amends the record at that time. The subject individual shall specify in each request:

(1) The system of records from which the record is retrieved;

(2) The particular record which he is seeking to correct or amend;

(3) Whether he is seeking an addition to or a deletion or substitution of the record; and,

(4) His reasons for requesting correction or amendment of the record.

(b) A request for correction or amendment of a record will be acknowledged within 10 working days of its receipt unless the request can be processed and the subject individual informed of the responsible Department official's decision on the request within that 10 day period.

(c) If the responsible Department official agrees that the record is not accurate, timely, or complete based on a preponderance of the evidence, the record will be corrected or amended. The record will be deleted without regard to its accuracy, if the record is not relevant or necessary to accomplish the Department function for which the record was provided or is maintained. In either case, the subject individual will be informed in writing of the correction, amendment, or deletion and, if accounting was made of prior disclosures of the record, all previous recipients of the record will be informed of the corrective action taken.

(d) If the responsible Department official does not agree that the record should be corrected or amended, the subject individual will be informed in writing of the refusal to correct or amend the record. He will also be informed that he may appeal the refusal to correct or amend his record to the appropriate appeal authority listed in § 5b.8 of this part. The appropriate appeal authority will be identified to the subject individual by name, title, and business address.

(e) Requests to correct or amend a record governed by the regulation of another government agency, *e.g.*, Civil Service Commission, Federal Bureau of Investigation, will be forwarded to such government agency for processing and the subject individual will be informed in writing of the referral.

§ 5b.8 Appeals of refusals to correct or amend records.

(a) *Processing the appeal.* (1) A subject individual who disagrees with a refusal to correct or amend his record may appeal the refusal in writing. All appeals shall be made to the following appeal authorities, or their designees, or successors in function:

(i) Assistant Secretary for Administration and Management for records of the Office of the Secretary, or where the initial refusal to correct or amend was made by another appeal authority. The appeal authority for an initial refusal by the Assistant Secretary for Administration and Management is the Under Secretary.

(ii) Assistant Secretary for Health for records of the Public Health Service including Office of Assistant Secretary for Health; Health Resources Administration; Health Services Administration; Alcohol, Drug Abuse, and Mental Health Administration; Center for Disease Control; National Institutes of Health; and Food and Drug Administration.

(iii) Assistant Secretary for Education for records of the Office of the Assistant Secretary for Education, National Center for Education Statistics, National Institute of Education, and Office of Education.

(iv) Assistant Secretary for Human Development for records of the Office of Human Development.

(v) Commissioner of Social Security for records of the Social Security Administration

(vi) Administrator, Social and Rehabilitation Service for the records of the Social and Rehabilitation Service.

(2) An appeal will be completed within 30 working days from its receipt by the appeal authority; *except that*, the appeal authority may for good cause extend this period for an additional 30 days. Should the appeal period be extended, the subject individual appealing the refusal to correct or amend the record will be informed in writing of the extension and the circumstances of the delay. The subject individual's request to amend or correct the record, the responsible Department official's refusal to correct or amend, and any other pertinent material relating to the appeal will be reviewed. No hearing will be held.

(3) If the appeal authority agrees that the record subject to the appeal should be corrected or amended, the record will be amended and the subject individual will be informed in writing of the correction or amendment. Where an accounting was made of prior disclosures of the record, all

previous recipients of the record will be informed of the corrective action taken.

(4) If the appeal is denied, the subject individual will be informed in writing:

(i) Of the denial and the reasons for the denial;

(ii) That he has a right to seek judicial review of the denial; and,

(iii) That he may submit to the responsible Department official a concise statement of disagreement to be associated with the disputed record and disclosed whenever the record is disclosed.

(b) *Notation and disclosure of disputed records.* Whenever a subject individual submits a statement of disagreement to the responsible Department official in accordance with paragraph (a)(4)(iii) of this section, the record will be noted to indicate that it is disputed. In any subsequent disclosure, a copy of the subject individual's statement of disagreement, will be disclosed with the record. If the responsible Department official deems it appropriate, a concise statement of the appeal authority's reasons for denying the subject individual's appeal may also be disclosed with the record. While the subject individual will have access to this statement of reasons, such statement will not be subject to correction or amendment. Where an accounting was made of prior disclosures of the record, all previous recipients of the record will be provided a copy of the subject individual's statement of disagreement, as well as the statement, if any, of the appeal authority's reasons for denying the subject individual's appeal.

§ 5b.9 Disclosure of records.

(a) *Consent to disclosure by a subject individual.* (1) Except as provided in paragraph (b) of this section authorizing disclosures of records without consent, no disclosure of a record will be made without the consent of the subject individual. In each case the consent, whether obtained from the subject individual at the request of the Department or whether provided to the Department by the subject individual on his own initiative, shall be in writing. The consent shall specify the individual, organizational unit or class of individuals or organizational units to whom the record may be disclosed, which record may be disclosed and, where applicable, during which time frame the record may be disclosed (*e.g.*, during the school year, while the subject individual is out of the country, whenever the subject individual is receiving specific services). A blanket consent to disclose all of a subject individual's records to unspecified individuals or organizational units will not be honored. The subject individual's identity and, where applicable (*e.g.*, where a subject individual gives consent to disclosure of a record to a specific individual), the identity of the individual to whom the record is to be disclosed shall be verified.

(2) A parent or guardian of any minor is not authorized to give consent to a disclosure of the minor's medical record.

(b) *Disclosures without the consent of the subject individual.* The disclosures listed in this paragraph may be made without the consent of the subject individual. Such disclosures are:

(1) To those officers and employees of the Department who have a need for the record in the performance of their duties. The responsible Department official may upon request of any officer or employee, or on his own initiative, determine what constitutes legitimate need.

(2) Required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, and Part 5 of this title.

(3) For a routine use as defined in paragraph (j) of § 5b.1 of this part. Routine uses will be listed in any notice of a system of records. Routine uses published in Appendix B are applicable to more than one system of records. Where applicable, notices of systems of records may contain references to the routine uses listed in Appendix B. Appendix B will be published with any compendium of notices of systems of records.

(4) To the Bureau of the Census for purposes of planning or carrying out a census or survey or related activity pursuant to the provisions of Title 13 U.S.C.

(5) To a recipient who has provided the agency with advance written as-

surance that the record will be used solely as a statistical research or reporting record; *Provided*, That, the record is transferred in a form that does not identify the subject individual.

(6) To the National Archives of the United States as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, or for evaluation by the Administrator of General Services or his designee to determine whether the record has such value.

(7) To another government agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of such government agency or instrumentality has submitted a written request to the Department specifying the record desired and the law enforcement activity for which the record is sought.

(8) To an individual pursuant to a showing of compelling circumstances affecting the health or safety of any individual if a notice of the disclosure is transmitted to the last known address of the subject individual.

(9) To either House of Congress, or to the extent of matter within its jurisdiction, any committee or subcommittee thereof, any joint committee of Congress or subcommittee of any such joint committee.

(10) To the Comptroller General, or any of his authorized representatives, in the course of the performance of the duties of the General Accounting Office.

(11) Pursuant to the order of a court of competent jurisdiction.

(c) *Accounting of disclosures.* (1) An accounting of all disclosures of a record will be made and maintained by the Department for 5 years or for the life of the record, whichever is longer; *except that*, such an accounting will not be made:

(i) For disclosures under paragraphs (b) (1) and (2) of this section; and,

(ii) For disclosures made with the written consent of the subject individual.

(2) The accounting will include:

(i) The date, nature, and purpose of each disclosure; and

(ii) The name and address of the person or entity to whom the disclosure is made.

(3) Any subject individual may request access to an accounting of disclosures of a record. The subject individual shall make a request for access to an accounting in accordance with the procedures in § 5b.5 of this part. A subject individual will be granted access to an accounting of the disclosures of a record in accordance with the procedures of this part which govern access to the related record. Access to an accounting of a disclosure of a record made under paragraph (b)(7) of this section may be granted at the discretion of the responsible Department official.

§ 5b.10 Parents and guardians.

For the purpose of this part, a parent or guardian of any minor or the legal guardian or any individual who has been declared incompetent due to physical or mental incapacity or age by a court of competent jurisdiction is authorized to act on behalf of an individual or a subject individual. Except as provided in paragraph (b)(2) of § 5b.5, of this part governing procedures for verifying an individual's identity, and paragraph (c) (2) of § 5b.6 of this part governing special procedures for notification of or access to a minor's medical records, an individual authorized to act on behalf of a minor or legal incompetent will be viewed as if he were the individual or subject individual.

§ 5b.11 Exempt systems.

(a) *General policy.* The Act permits certain types of specific systems of records to be exempt from some of its requirements. It is the policy of the Department to exercise authority to exempt systems of records only in compelling cases.

(b) *Specific systems of records exempted.* (1) Those systems of records listed in paragraph (b)(2) of this section are exempt from the following provisions of the Act and this part:

(i) 5 U.S.C. 552a(c)(3) and paragraph (c)(2) of § 5b.9 of this part which require a subject individual to be granted access to an accounting of disclosures of a record.

(ii) 5 U.S.C. 552a(d) (1) through (4) and (f) and §§ 5b.6, 5b.7, and 5b.8 of this part relating to notification of or access to records and correction or amendment of records.

(iii) 5 U.S.C. 552a(e)(4) (G) and (H) which require inclusion of information about Department procedures for notification, access, and correction or amendment of records in the notice for the systems of records.

(iv) 5 U.S.C. 552(e)(3) and paragraph (a)(3) of § 5b.4 of this part which require that an individual asked to provide a record to the Department be informed of the authority for providing the record (including whether the providing of the record is mandatory or voluntary, the principal purposes for maintaining the record, the routine uses for the record, and what effect his refusal to provide the record may have on him), and if the record is not required by statute or Executive Order to be provided by the individual, he agrees to provide the record. This exemption applies only to an investigatory record compiled by the Department for criminal law enforcement purposes in a system of records exempt under subsection (j)(2) of the Act to the extent that these requirements would prejudice the conduct of the investigation.

(2) The following systems of records are exempt from those provisions of the Act and this part listed in paragraph (b) (1) of this section.

(i) Pursuant to subsection (j)(2) of the Act:

(A) The Saint Elizabeths Hospital's Court-Ordered Forensic Investigatory Materials Files; and

(B) The Investigatory Material Compiled for Law Enforcement Purposes System, HHS.

(ii) Pursuant to subsection (k)(2) of the Act:

(A) The General Criminal Investigation Files, HHS/SSA;

(B) The Criminal Investigations File, HHS/SSA; and,

(C) The Program Integrity Case Files, HHS/SSA.

(D) Civil and Administrative Investigative Files of the Inspector General, HHS/OS/OIG.

(E) Complaint Files and Log. HHS/OS/OCR.

(iii) Pursuant to subsection (k)(4) of the Act:

(A) The Health and Demographic Surveys Conduct in Random Samples of the U.S. Population;

(B) The Health Manpower Inventories and Surveys;

(C) The Vital Statistics for Births, Deaths, Fetal Deaths, Marriages and Divorces Occurring in the U.S. during Each Year; and,

(D) The Maryland Psychiatric Case Register.

(E) The Health Resources Utilization Statistics, DHHS/OASH/NCHS.

(F) National Medical Expenditure Survey Records. HHS/OASH/NCHSR.

(iv) Pursuant to subsection (k)(5) of the Act:

(A) The Investigatory Material Compiled for Security and Suitability Purposes System, HHS; and,

(B) The Suitability for Employment Records, HHS.

(v) Pursuant to subsections (j)(2), (k)(2), and (k)(5) of the Act:

(A) The Clinical Investigatory Records, HHS/FDA;

(B) The Regulated Industry Employee Enforcement Records, HHS/FDA;

(C) The Employee Conduct Investigative Records, HHS/FDA; and,

(D) The Service Contractor Employee Investigative Records, HHS/FDA.

(vi) Pursuant to subsection (k)(6) of the Act:

(A) The Personnel Research and Merit Promotion Test Records, HHS/SSA/OMA.

(c) *Notification of or access to records in exempt systems of records.* (1) Where a system of records is exempt as provided in paragraph (b) of this section, any individual may nonetheless request notification of or access to a record in that system. An individual shall make requests for notification of or access to a record in an exempt system of records in accordance with the procedures of §§ 5b.5 and 5b.6 of this part.

(2) An individual will be granted notification of or access to a record in an

exempt system but only to the extent such notification or access would not reveal the identity of a source who furnished the record to the Department under an express promise, and prior to September 27, 1975 an implied promise, that his identity would be held in confidence, if:

(i) The record is in a system of records which is exempt under subsection (k)(2) of the Act and the individual has been, as a result of the maintenance of the record, denied a right, privilege, or benefit to which he would otherwise be eligible; or,

(ii) The record is in a system of records which is exempt under subsection (k)(5) of the Act.

(3) If an individual is not granted notification of or access to a record in a system of records exempt under subsections (k) (2) and (5) of the Act in accordance with this paragraph, he will be informed that the identity of a confidential source would be revealed if notification of or access to the record were granted to him.

(d) *Discretionary actions by the responsible Department official.* Unless disclosure of a record to the general public is otherwise prohibited by law, the responsible Department official may in his discretion grant notification of or access to a record in a system of records which is exempt under paragraph (b) of this section. Discretionary notification of or access to a record in accordance with this paragraph will not be a precedent for discretionary notification of or access to a similar or related record and will not obligate the responsible Department official to exercise his discretion to grant notification of or access to any other record in a system of records which is exempt under paragraph (b) of this section.

[40 FR 47409, Oct. 8, 1975, as amended at 43 FR 40229, Sept. 11, 1978; 47 FR 57040, Dec. 22, 1982; 49 FR 14108, Apr. 10, 1984; 51 FR 41352, Nov. 14, 1986]

§ 5b.12 Contractors.

(a) All contracts entered into on or after September 27, 1975 which require a contractor to maintain or on behalf of the Department to maintain, a system of records to accomplish a Department function must contain a provision requiring the contractor to comply with the Act and this part.

(b) All unexpired contracts entered into prior to September 27, 1975 which require the contractor to maintain or on behalf of the Department to maintain, a system of records to accomplish a Department function will be amended as soon as practicable to include a provision requiring the contractor to comply with the Act and this part. All such contracts must be so amended by July 1, 1976 unless for good cause the appeal authority identified in § 5b.8 of this part authorizes the continuation of the contract without amendment beyond that date.

(c) A contractor and any employee of such contractor shall be considered employees of the Department only for the purposes of the criminal penalties of the Act, 5 U.S.C. 552a(i), and the employee standards of conduct listed in Appendix A of this part where the contract contains a provision requiring the contractor to comply with the Act and this part.

(d) This section does not apply to systems of records maintained by a contractor as a result of his management discretion, *e.g.*, the contractor's personnel records.

§ 5b.13 Fees.

(a) *Policy.* Where applicable, fees for copying records will be charged in accordance with the schedule set forth in this section. Fees may only be charged where an individual requests that a copy be made of the record to which he is granted access. No fee may be charged for making a search of the system of records whether the search is manual, mechanical, or electronic. Where a copy of the record must be made in order to provide access to the record (*e.g.*, computer printout where no screen reading is available), the copy will be made available to the individual without cost. Where a medical record is made available to a representative designated by the individual or to a physician or health professional designated by a parent or guardian under § 5b.6 of this part, no fee will be charged.

(b) *Fee schedule.* The fee schedule for the Department is as follows:

(1) Copying of records susceptible to photocopying—$.10 per page.

(2) Copying records not susceptible to photocopying (*e.g.*, punch cards or magnetic tapes)—at actual cost to be determined on a case-by-case basis.

(3) No charge will be made if the total amount of copying does not exceed $25.

APPENDIX A—EMPLOYEE STANDARDS OF CONDUCT

(a) *General.* All employees are required to be aware of their responsibilities under the Privacy Act of 1974, 5 U.S.C. 552a. Regulations implementing the Act are set forth in 45 CFR 5b. Instruction on the requirements of the Act and regulation shall be provided to all new employees of the Department. In addition, supervisors shall be responsible for assuring that employees who are working with systems of records or who undertake new duties which require the use of systems of records are informed of their responsibilities. Supervisors shall also be responsible for assuring that all employees who work with such systems of records are periodically reminded of the requirements of the Act and are advised of any new provisions or interpretations of the Act.

(b) *Penalties.* (1) All employees must guard against improper disclosure of records which are governed by the Act. Because of the serious consequences of improper invasions of personal privacy, employees may be subject to disciplinary action and criminal prosecution for knowing and willful violations of the Act and regulation. In addition, employees may also be subject to disciplinary action for unknowing or unwillful violations, where the employee had notice of the provisions of the Act and regulations and failed to inform himself sufficiently or to conduct himself in accordance with the requirements to avoid violations.

(2) The Department may be subjected to civil liability for the following actions undertaken by its employees:

(a) Making a determination under the Act and §§ 5b.7 and 5b.8 of the regulation not to amend an individual's record in accordance with his request, or failing to make such review in conformity with those provisions;

(b) Refusing to comply with an individual's request for notification of or access to a record pertaining to him;

(c) Failing to maintain any record pertaining to any individual with such accuracy, relevance, timeliness, and completeness as is necessary to assure fairness in any determination relating to the qualifications, character, rights, or opportunities of, or benefits to the individual that may be made on the basis of such a record, and consequently a determination is made which is adverse to the individual; or

(d) Failing to comply with any other provision of the Act or any rule promulgated thereunder, in such a way as to have an adverse effect on an individual.

(3) An employee may be personally subject to criminal liability as set forth below and in 5 U.S.C. 552a (i):

(a) Any officer or employee of an agency, who by virtue of his employment or official position, has possession of, or access to, agency records which contain individually identifiable information the disclosure of which is prohibited by the Act or by rules or regulations established thereunder, and who, knowing that disclosure of the specific material is so prohibited, willfully discloses the material in any manner to any person or agency not entitled to receive it, shall be guilty of a misdemeanor and fined not more than $5,000.

(b) Any officer or employee of any agency who willfully maintains a system of records without meeting the notice requirements [of the Act] shall be guilty of a misdemeanor and fined not more than $5,000.

(c) *Rules Governing Employees Not Working With Systems of Records.* Employees whose duties do not involve working with systems of records will not generally disclose to any one, without specific authorization from their supervisors, records pertaining to employees or other individuals which by reason of their official duties are available to them. Notwithstanding the above, the following records concerning Federal employees are a matter of public record and no further authorization is necessary for disclosure:

(1) Name and title of individual.

(2) Grade classification or equivalent and annual rate of salary.

(3) Position description.

(4) Location of duty station, including room number and telephone number.

In addition, employees shall disclose records which are listed in the Department's Freedom of Information Regulation as being available to the public. Requests for other records will be referred to the responsible Department official. This does not preclude employees from discussing matters which are known to them personally, and without resort to a record, to official investigators of Federal agencies for official purposes such as suitability checks, Equal Employment Opportunity investigations, adverse action proceedings, grievance proceedings, etc.

(d) *Rules governing employees whose duties require use or reference to systems of records.* Employees whose official duties require that they refer to, maintain, service, or otherwise deal with systems of records (hereinafter referred to as "Systems Employees") are governed by the general provisions. In addition, extra precautions are required and systems employees are held to higher standards of conduct.

(1) Systems Employees shall:

(a) Be informed with respect to their responsibilities under the Act;

(b) Be alert to possible misuses of the system and report to their supervisors any potential or actual use of the system which they believe is not in compliance with the Act and regulation;

(c) Make a disclosure of records within the Department only to an employee who has a legitimate need to know the record in the course of his official duties;

(d) Maintain records as accurately as practicable.

(e) Consult with a supervisor prior to taking any action where they are in doubt whether such action is in conformance with the Act and regulation.

(2) Systems Employees shall not:

(a) Disclose in any form records from a system of records except (1) with the consent or at the request of the subject individual; or (2) where its disclosure is permitted under § 5b.9 of the regulation.

(b) Permit unauthorized individuals to be present in controlled areas. Any unauthorized individuals observed in controlled areas shall be reported to a supervisor or to the guard force.

(c) Knowingly or willfully take action which might subject the Department to civil liability.

(d) Make any arrangements for the design development, or operation of any system of records without making reasonable effort to provide that the system can be maintained in accordance with the Act and regulation.

(e) *Contracting officers.* In addition to any applicable provisions set forth above, those employees whose official duties involve entering into contracts on behalf of the Department shall also be governed by the following provisions:

(1) *Contracts for design, or development of systems and equipment.* No contract for the design or development of a system of records, or for equipment to store, service or maintain a system of records shall be entered into unless the contracting officer has made reasonable effort to ensure that the product to be purchased is capable of being used without violation of the Act or regulation. Special attention shall be given to provision of physical safeguards.

(2) *Contracts for the operation of systems of records.* A review by the Contracting Officer, in conjunction with other officials whom he feels appropriate, of all proposed contracts providing for the operation of systems of records shall be made prior to execution of the contracts to determine whether operation of the system of records is for the purpose of accomplishing a Department function. If a determination is made that the operation of the system is to accomplish a Department function, the contracting officer shall be responsible for including in the contract appropriate provisions to apply the provisions of the Act and regulation to the system, including prohibitions against improper release by the contractor, his employees, agents, or subcontractors.

(3) *Other service contracts.* Contracting officers entering into general service contracts shall be responsible for determining the appropriateness of including provisions in the contract to prevent potential misuse (inadvertent or otherwise) by employees, agents, or subcontractors of the contractor.

(f) *Rules Governing Responsible Department Officials.* In addition to the requirements for Systems Employees, responsible Department officials shall:

(1) Respond to all requests for notification of or access, disclosure, or amendment of records in a timely fashion in accordance with the Act and regulation;

(2) Make any amendment of records accurately and in a timely fashion;

(3) Inform all persons whom the accounting records show have received copies of the record prior to the amendments of the correction; and

(4) Associate any statement of disagreement with the disputed record, and

(a) Transmit a copy of the statement to all persons whom the accounting records show have received a copy of the disputed record, and

(b) Transmit that statement with any future disclosure.

Appendix B—Routine Uses Applicable to More Than One System of Records Maintained by HHS

(1) In the event that a system of records maintained by this agency or carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether federal, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

(2) Referrals may be made of assignments of research investigators and project monitors to specific research projects to the Smithsonian Institution to contribute to the Smithsonian Science Information Exchange, Inc.

(3) In the event the Department deems it desirable or necessary, in determining whether particular records are required to be disclosed under the Freedom of Information Act, disclosure may be made to the Department of Justice for the purpose of obtaining its advice.

(4) A record from this system of records may be disclosed as a "routine use" to a federal, state or local agency maintaining civil, criminal or other relevant enforcement records or other pertinent records, such as current licenses, if necessary to obtain a record relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit.

A record from this system of records may be disclosed to a Federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter.

(5) In the event that a system of records maintained by this agency to carry out its function indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether state or local charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

(6) Where Federal agencies having the power to subpoena other Federal agencies' records, such as the Internal Revenue Service or the Civil Rights Commission, issue a subpoena to the Department for records in this system of records, the Department will make such records available.

(7) Where a contract between a component of the Department and a labor organization recognized under E.O. 11491 provides that the agency will disclose personal records relevant to the organization's mission, records in this system of records may be disclosed to such organization.

(8) Where the appropriate official of the Department, pursuant to the Department's Freedom of Information Regulation determines that it is in the public interest to disclose a record which is otherwise exempt from mandatory disclosure, disclosure may be made from this system of records.

(9) The Department contemplates that it will contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.

(10)-(99) [Reserved]

(100) To the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.

(101) To individuals and organizations, deemed qualified by the Secretary to carry out specific research solely for the purpose of carrying out such research.

(102) To organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review.

(103) Disclosures in the course of employee discipline or competence determination proceedings.

APPENDIX C—DELEGATIONS OF AUTHORITY [RESERVED]

PART 6—INVENTIONS AND PATENTS (GENERAL)

Sec.

6.0 General policy.
6.1 Publication or patenting of inventions.
6.2 General responsibility.
6.3 Licensing of Government-owned patents.
6.4 Central records; confidentiality.

AUTHORITY: Reorg. Plan No. 1 of 1953, 18 FR 2053; 3 CFR, 1953 Supp. E.O. 10096, 15 FR 391; 3 CFR, 1950 Supp.

§ 6.0 General policy.

Inventions developed through the resources and activities of the Department are a potential resource of great value to the public health and welfare. It is the policy of the Department:

(a) To safeguard the public interest in inventions developed by Department employees, contractors and grantees with the aid of public funds and facilities;

(b) To encourage and recognize individual and cooperative achievement in research and investigations; and

(c) To establish a procedure, consistent with pertinent statutes, Executive orders and general Government regulations, for the determination of rights and obligations relating to the patenting of inventions.

[20 FR 6747, Sept. 14, 1955. Redesignated at 31 FR 12842, Oct. 1, 1966]

§ 6.1 Publication or patenting of inventions.

It is the general policy of the Department that the results of Department research should be made widely, promptly and freely available to other research workers and to the public. This availability can generally be adequately preserved by the dedication of a Government-owned invention to the public. Determinations to file a domestic patent application on inventions in which the Department has an interest will be made where the circumstances indicate that this is desirable in the public interest, and if it is practicable to do so. Department determinations not to apply for a domestic patent on employee inventions are subject to review and approval by the Commissioner of Patents. Except where deemed necessary for protecting the patent claim, the fact that a patent application has been or may be filed will not require any departure from normal policy regarding the dissemination of the results of Department research.

[28 FR 2990, Mar. 27, 1963. Redesignated at 31 FR 12842, Oct. 1, 1966]

§ 6.2 General responsibility.

The Assistant Secretary (Health and Scientific Affairs) is responsible for the administration of the invention and patent program of the Department and the determination of rights in inventions and patents in which the Department has an interest.

[31 FR 12842, Oct. 1, 1966]

§ 6.3 Licensing of Government-owned patents.

(a) Licenses to practice inventions covered by patents and pending patent applications owned by the U.S. Government as represented by this Department will generally be royalty free, revocable and nonexclusive. They will normally be issued to all applicants and will generally contain no limitations or standards relating to the quality or testing of the products to be manufactured, sold, or distributed thereunder.

(b) Where it appears however that the public interest will be served under the circumstances of the particular case by licenses which impose conditions, such as those relating to quality or testing of products, requirement of payment of royalties to the Government, etc., or by the issuance of limited exclusive licenses by the Assistant Secretary for Health and Scientific Affairs after notice and opportunity for hearing thereon, such licenses may be issued.

[34 FR 15560, Oct. 7, 1969]

§ 6.4 Central records; confidentiality.

Central files and records shall be maintained of all inventions, patents, and licenses in which the Department has an interest, together with a record of all licenses issued by the Department under such patents. Invention reports required from employees or others for the purpose of obtaining determinations of ownership, and documents and information obtained for the purpose of prosecuting patent applications shall be confidential and shall be disclosed only as required for official purposes or with the consent of the inventor.

[20 FR 6747, Sept. 14, 1955]

PART 7—EMPLOYEE INVENTIONS

Sec.

7.0 Who are employees.
7.1 Duty of employee to report inventions.
7.3 Determination as to domestic rights.
7.4 Option to acquire foreign rights.
7.7 Notice to employee of determination.
7.8 Employee's right of appeal.

AUTHORITY: Reorg. Plan No. 1 of 1953, 18 FR 2053; 3 CFR 1953 Supp. E.O. 10096, 15 FR 391; 3 CFR. 1950 Supp. and E.O. 10930, 26 FR 2583; 3 CFR 1961 Supp.

§ 7.0 Who are employees.

As used in this part, the term "Government employee" means any officer or employee, civilian or military, except such part-time employees or part-time consultants as may be excluded therefrom by a determination made in writing by the head of the employee's office or constituent organization, pursuant to an exemption approved by the Commissioner of Patents that to include him or them would be impracticable or inequitable, given the reasons therefor. A person shall not be considered to be a part-time employee or part-time consultant for this purpose unless the terms of his employment contemplate that he shall work for less than the minimum number of hours per day, or less than a minimum number of days per week, or less than the minimum number of weeks per year, regularly required of full-time employees of his class.

[27 FR 7986, Aug. 10, 1962]

§ 7.1 Duty of employee to report inventions.

Every Department employee is required to report to the Assistant Secretary (Health and Scientific Affairs) in accordance with the procedures established therefor, every invention made by him (whether or not jointly with others) which bears any relation to his official duties or which was made in whole or in any part during working hours, or with any contribution of Government facilities, equipment, material, funds, or information, or of time or services of other Government employees on official duty.

[31 FR 12842, Oct. 1, 1966]

§ 7.3 Determination as to domestic rights.

The determination of the ownership of the domestic right, title, and interest in and to an invention which is or may be patentable, made by a Government employee while under the administrative jurisdiction of the Department, shall be made in writing by the Assistant Secretary (Health and Scientific Affairs), in accordance with the provisions of Executive Order 10096 and Government-wide regulations issued thereunder by the Commissioner of Patents as follows:

(a) The Government as represented by the Assistant Secretary (Health and Scientific Affairs) shall obtain the entire domestic right, title and interest in and to all inventions made by any Government employee (1) during working hours, or (2) with a contribution by the Government of facilities, equipment, materials, funds, or information, or of time or services of other Government employees on official duty, or (3) which bear a direct relation to or are made in consequence of the official duties of the inventor.

(b) In any case where the contribution of the Government, as measured by any one or more of the criteria set forth in paragraph (a) of this section, to the invention is insufficient equitably to justify a requirement of assignment to the Government of the entire domestic right, title and interest in and to such invention, or in any case where the Government has insufficient interest in an invention to obtain the entire domestic right, title, and interest therein (although the Government could obtain same under paragraph (a) of this section), the Department, subject to the approval of the Commissioner, shall leave title to such invention in the employee, subject, however, to the reservation to the Government of a nonexclusive, irrevocable, royalty-free license in the invention with power to grant licenses for all governmental purposes, such reservation to appear, where practicable, in any patent, domestic or foreign, which may issue on such invention.

(c) In applying the provisions of paragraphs (a) and (b) of this section, to the facts and circumstances relating to the making of any particular invention, it shall be presumed that an invention made by an employee who is employed or assigned (1) to invent or improve or perfect any art, machine, manufacture, or composition of matter, (2) to conduct or perform research, development work, or both, (3) to supervise, direct, coordinate, or review Government financed or conducted research, development work, or both, or (4) to act in a liaison capacity among governmental or nongovernmental agencies or individuals engaged in such work, falls within the provisions of paragraph (a) of this section, and it shall be presumed that any invention made by any other employee falls within the provisions of paragraph (b) of this section. Either presumption may be rebutted by a showing of the facts and circumstances and shall not preclude a determination that these facts and circumstances justify leaving the entire right, title and interest in and to the invention in the Government employee, subject to law.

(d) In any case wherein the Government neither (1) obtains the entire domestic right, title and interest in and to an invention pursuant to the provisions of paragraph (a) of this section, nor (2) reserves a nonexclusive, irrevocable, royalty-free license in the invention, with power to grant licenses for all governmental purposes, pursuant to the provisions of paragraph (b) of this section, the Government shall leave the entire right, title and interest in and to the invention in the Government employee, subject to law.

[27 FR 7986, Aug. 10, 1962, as amended at 31 FR 12842, Nov. 1, 1966]

§ 7.4 Option to acquire foreign rights.

In any case where it is determined that all domestic rights should be assigned to the Government, it shall further be determined, pursuant to Executive Order 9865 and Governmentwide regulations issued thereunder, that the Government shall reserve an option to require the assignment of such rights in all or in any specified foreign countries. In case where the inventor is not required to assign the patent rights in any foreign country or countries to the Government or the Government fails to exercise its option within such period of time as may be provided by regulations issued by the Commissioner of Patents, any application for a patent which may be filed in such country or countries by the inventor or his assignee shall nevertheless be subject to a nonexclusive, irrevocable, royalty-free license to the Government for all governmental purposes, including the power to issue sublicenses for use in behalf of the Government and/or in furtherance of the foreign policies of the Government.

[27 FR 7987, Aug. 10, 1962]

§ 7.7 Notice to employee of determination.

The employee-inventor shall be notified in writing of the Department's determination of the rights to his invention and of his right of appeal, if any. Notice need not be given if the employee stated in writing that he would agree to the determination of ownership which was in fact made.

[31 FR 12842, Oct. 1, 1966]

§ 7.8 Employee's right of appeal.

An employee who is aggrieved by a determination of the Department may appeal to the Commissioner of Patents, pursuant to section 4(d) of Executive Order 10096, as amended by Executive Order 10930, and regulations issued thereunder, by filing a written appeal with the Commissioner, in duplicate, and a copy of the appeal with the Assistant Secretary (Health and Scientific Affairs), within 30 days (or such longer period as the Commissioner may, for good cause, fix in any case) after receiving written notice of such determination.

[27 FR 7986, Aug. 10, 1962, as amended at 31 FR 12842, Oct. 1, 1966]

PART 8—INVENTIONS RESULTING FROM RESEARCH GRANTS, FELLOWSHIP AWARDS, AND CONTRACTS FOR RESEARCH

Sec.

8.0 Policy.
8.1 Conditions to be included in research grants.
8.2 Determination as to domestic rights.
8.3 Licenses to the Government.
8.4 Option to acquire foreign rights.
8.5 Fellowships.
8.6 Contracts for research.
8.7 Cancer chemotherapy industrial research contracts.
8.8 Screening of compounds generated under DHHS grants and awards.

AUTHORITY: Reorg. Plan No. 1 of 1953, 18 FR 2053; 3 CFR, 1953 Supp. E.O. 9865, 12 FR 3907; 3 CFR, 1947 Cum. Supp. E.O. 10096, 15 FR 391; 3 CFR, 1950 Supp.

§ 8.0 Policy.

(a) The Department of Health and Human Services each year is expending large sums in the form of grants for research. These grants are made primarily by the Public Health Service in carrying out its broad responsibility under the Public Health Service Act to promote and coordinate research in the field of health and to make available information concerning such research and its practical application.

The scientific and technological advances attributable, in varying degrees to this expenditure of public funds frequently include patentable inventions.

(b) The Department, as a matter of policy, takes the position that the results of research supported by grants of public moneys should be utilized in the manner which would best serve the public interest. It is believed that the public interest will in general be best served if inventive advances resulting therefrom are made freely available to the Government, to science, to industry, and to the general public.

(c) On the other hand, in some cases it may be advisable to permit a utilization of the patent process in order to foster an adequate commercial development to make a new invention widely available. Moreover, it is recognized that inventions frequently arise in the course of research activities which also receive substantial support from other sources, as well as from the Federal grant. It would not be consistent with the cooperative nature of such activities to attribute a particular invention primarily to support received from any one source. In all these cases the Department has a responsiblity to see that the public use of the fruits of the research will not be unduly restricted or denied.

(d) The following conditions have been adopted to govern the treatment of inventions made in these various types of situations. They are designed to afford suitable protection to the public interest while giving appropriate recognition to the legitimate interests of others who have contributed to the invention.

[20 FR 6749, Sept. 14, 1955]

§ 8.1 Conditions to be included in research grants.

Subject to legislative directives or Executive orders providing otherwise, all grants in aid of research shall provide as a condition that any invention arising out of the activities assisted by the grant shall be promptly and fully reported, and shall provide either:

(a) That the ownership and manner of disposition of all rights in and to such invention shall be subject to determination by the Assistant Secretary (Health and Scientific Affairs) or

(b) That the ownership and disposition of all domestic rights shall be left for determination by the grantee institution in accordance with the grantee's established policies and procedures, with such modifications as may be agreed upon and specified in the grant, provided the Assistant Secretary (Health and Scientific Affairs) finds that these are such as to assure that the invention will be made available without unreasonable restrictions or excessive royalties, and provided the Government shall receive a royalty-free license, with a right to issue sublicenses as provided in § 8.3, under any patent applied for or obtained upon the invention.

(c) Wherever practicable, any arrangement with the grantee pursuant to paragraph (b) of this section shall provide in accordance with Executive Order 9865 that there be reserved to the Government an option, for a period to be prescribed, to file foreign patent applications upon the invention.

[20 FR 6749, Sept. 14, 1955, as amended at 31 FR 12842, Oct. 1, 1966]

§ 8.2 Determination as to domestic rights.

Rights in any invention not subject to disposition by the grantee pursuant to § 8.1(b) are for determination by the Assistant Secretary (Health and Scientific Affairs) as follows:

(a) If he finds that there is adequate assurance that the invention will either be effectively dedicated to the public, or that any patent which may be obtained thereunder will be generally available for royalty-free and nonexclusive licensing, the effectuation of these results may be left to the grantee.

(b) If he finds that the invention will thereby be more adequately and quickly developed for widest use and that there are satisfactory safeguards against unreasonable royalties and repressive practices, the invention may be assigned to a competent organization for development and administration for the term of the patent or such lesser period as may be deemed necessary.

(c) If he finds that the interest of another contributing Government agency is paramount to the interest of the Department of Health and Human Services, or when otherwise legally required or in the public interest, the invention may be left for disposition by that agency in accordance with its own policy.

(d) In all other cases, he shall require that all domestic rights in the invention shall be assigned to the United States unless he determines that the invention is of such doubtful importance or the Government's equity in the invention is so minor that protective measures, except as provided in § 8.3, are not necessary in the public interest.

[20 FR 6749, Sept. 14, 1955, as amended at 31 FR 12842, Oct. 1, 1966]

§ 8.3 Licenses to the Government.

Any arrangement or determination as to the disposition of rights in inventions pursuant to §§ 8.1, 8.2, 8.5 or 8.6 shall require that there be reserved under any patent application or patent thereon, domestic or foreign, a nonexclusive, irrevocable, royalty-free license to the Government with power to sublicense for all governmental purposes.

[22 FR 9696, Dec. 4, 1957]

§ 8.4 Option to acquire foreign rights.

In any case where it is determined that all domestic rights should be assigned to the Government, there shall be reserved to the Government, pursuant to Executive Order 9865 (3 CFR, 1943-1948 Comp.) and Government-wide regulations issued thereunder, an option to require the assignment of all rights in the invention in all or in any specified foreign countries. In any case where the inventor is not required to assign the patent rights in any foreign country or countries to the Government, or the Government fails to exercise its option within such period of time as may be provided by regulations issued by the Chairman of the Government Patents Board any application for a patent which may be filed in such country or countries by the inventor or his assignee shall nevertheless be subject to a nonexclusive, irrevocable, royalty-free license to the Government for all governmental purposes, including the power to sublicense for all governmental purposes.

[20 FR 6750, Sept. 14, 1955]

§ 8.5 Fellowships.

In the discretion of the Assistant Secretary (Health and Scientific Affairs), the award of a fellowship to a person not a Government employee may provide for the reporting of any invention made during the term thereof, and for its disposition in accordance with the provisions of § 8.1(a) or for its disposition by the institution at which the research was performed in accordance with its established policies, if applicable to such an invention, which meet the requirements of paragraph (b) of such section.

[22 FR 9695, Dec. 4, 1957, as amended at 31 FR 12842, Oct. 1, 1966]

§ 8.6 Contracts for research.

(a) Contracts for research, with other than nonprofit institutions, shall provide that any invention first conceived or actually reduced to practice in the course of the performance of the contract shall be promptly and fully reported to the Assistant Secretary (Health and Scientific Affairs) for determination by him as to the manner of disposition of all rights in and to such invention, including the right to require assignment of all rights to the United States or dedication to the public. In the exercise of this power the organization head will be guided by the policy specified in § 8.2 with respect to grants.

(b) Contracts for research with nonprofit institutions shall contain provisions as in paragraph (a) of this section except that, if it is determined that the institution's policies and procedures are acceptable as meeting the requirements of § 8.1(b) with respect to grants, the contract may provide, with such special stipulations in the contract as may be deemed necessary in the public interest, for leaving the ownership and disposition of all domestic rights for determination by the contracting institution in accordance with such policies and procedures.

[23 FR 1215, Feb. 27, 1958, as amended at 31 FR 12842, Oct. 1, 1966]

§ 8.7 Cancer chemotherapy industrial research contracts.

Notwithstanding the provisions of § 8.6, the Surgeon General in the negotiation of contracts with other than nonprofit organizations for the cancer chemotherapy research program shall be subject only to such limitations and alternatives as the Assistant Secretary (Health and Scientific Affairs) may approve for such program.

[22 FR 9696, Dec. 4, 1957, as amended at 31 FR 12842, Oct. 1, 1966]

§ 8.8 Screening of compounds generated under DHHS grants and awards.

(a) *General policy.* (1) Chemical compounds having potential medicinal and other utilities are often synthesized or identified during the course of research financed under DHHS research grants and awards. Reporting, filing patent applications on, and determining ownership in inventions relating to such compounds pose problems which require special attention. After a compound has been synthesized, it generally will not constitute a patentable invention under the patent laws of the United States until a specific utility for the compound has been established. It is the policy of the Department that all compounds synthesized or identified during the course of grant-supported research should be adequately screened and tested in Government or non-Government facilities in order that all possible utilities may be ascertained and that any promising compounds may be fully developed for widest possible use. The Department encourages the utilization, whenever appropriate, of the screening services of the Cancer Chemotherapy National Service Center and the Walter Reed Army Institute of Research.

(2) It is the policy of the Department notwithstanding anything to the contrary under patent law of the United States or requirements of U.S. Patent Office practice, to acquire no ownership rights to inventions claiming novel methods of using compounds, where such use inventions are first conceived and reduced to practice solely by the screening or testing organization without the use of grant funds.

(b) *Screening performed with use of grant funds.* Where nongovernmental facilities are utilized for screening services to be performed and paid for by the grantee (as used in this section, the term "grantee" refers to awardees in addition grantee (as used in this section, the term to grantee institutions) with grant funds, the grantee shall obtain an agreement with the screening organization providing that the screener shall promptly report to the grantee the details of any positive findings of utility for the compound and that all invention rights relating to the compound and its utility shall, as between the grantee and the screener, vest in the grantee. Upon receipt of such report of positive findings, the grantee shall promptly forward copies to DHHS. Ownership of all invention rights to the compound or reported utilities shall be subject to the disposition by the Assistant Secretary (Health and Scientific Affairs) as provided by the terms of the grant or award in accordance with § 8.2, except that where the grantee institution has entered into an Institutional Patent Agreement with the Department pursuant to § 8.1(b), ownership of the invention rights shall be in accordance with the terms of that Agreement.

(c) *Screening performed without the use of grant funds.* Where screening is to be performed at nongovernmental facilities without the use of grant funds, the grantee may proceed to have compounds screened under one of the following arrangements:

(1) *Institutional Patent Agreement.* Where the grantee institution has entered into an Institutional Patent Agreement with the Department under § 8.1(b) of the Department Patent Regulations, the grantee shall enter into an agreement with the screener which shall be consistent with, and will permit the grantee to fully comply with its obligations under such Institutional Patent Agreement. The agreement with the screener shall, as a minimum, provide that ownership of patent rights to inventions resulting from the screening process shall vest, depending on the law of in-

ventorship, in the grantee, the screener, or both, except that such agreement may leave to screening or testing organizations ownership rights to inventions claiming novel methods of using compounds, where such use inventions are first conceived and reduced to practice solely by the screening or testing organization without the use of grant awards. The grantee shall administer all invention rights to the compound and all other invention rights vested in the grantee in accordance with the terms of the Institutional Patent Agreement.

(2) *Patent Agreements for Screening.* Where an Institutional Patent Agreement is not in effect, the grantee shall enter into an agreement with a screener to govern disposition of rights to inventions resulting from the screening. Such agreements shall be in the form prescribed by or as may be approved by the Department and shall be consistent with the policy set forth in paragraph (a) of this section.

(3) *Determination of invention rights prior to screening.* Where a grantee has not entered into an Institutional Patent Agreement, it may, prior to making arrangements for screening, petition the Assistant Secretary (Health and Scientific Affairs) requesting a determination that invention rights pertaining to an identified compound be assigned to the grantee for administration, pursuant to the provisions of § 8.2(b). Determinations under § 8.2(b) normally permit the grantee to grant exclusive licenses for a limited period of time. Such petition must demonstrate that an assignment is required in order to achieve effective screening of the compound and any resulting inventions will thereby be more adequately and quickly developed for widest use.

[34 FR 201, Jan. 7, 1969]

PART 9—USE OF HHS RESEARCH FACILITIES BY ACADEMIC SCIENTISTS, ENGINEERS, AND STUDENTS

Sec.
9.1 Purpose.
9.2 Policy.
9.3 Delegations of authority.
9.4 Criteria.
9.5 Restrictions.

AUTHORITY: 27 Stat. 395, as amended; 20 U.S.C. 91.

SOURCE: 34 FR 18938, Nov. 27, 1969, unless otherwise noted.

§ 9.1 Purpose.

To enhance the availability of DHHS scientific research and study facilities to academic scientists, engineers, and qualified students.

§ 9.2 Policy.

It is the policy of the Department of Health and Human Services in accordance with the policy of the President announced on February 21, 1969, to make research and study facilities of the Department readily available to the scientific community, especially qualified academic scientists and engineers. Unique, unusual, and expensive-to-duplicate facilities at laboratories and other study and research facilities of the Department will be made available to the national scientific community, to the maximum extent practical without serious detriment to the missions of those facilities. It is also the policy of the Department to permit qualified students and graduates of institutions of learning in the several States, and territories, as well as the District of Columbia, to use study and research facilities of the Department. When such facilities are used by academic scientists, engineers, and students, the costs incurred for the operation of the unique or unusual research facilities, as well as of the other facilities, should be funded by the operating agency responsible for the operation of that facility, except for any significant incremental costs incurred in support of research not directly related to an HHS mission.

§ 9.3 Delegations of authority.

(a) The heads of operating agencies are delegated authority for negotiations and decisions as to the use of Department facilities by qualified academic scientists, engineers, and students.

(b) The heads of operating agencies may (and are encouraged to) redelegate to the heads of their respective component organizations, with the power to further redelegate to laboratory directors, the authority for negotiations and decisions as to the use of departmental facilities. Appropriate use shall be made of advisory groups in formulating their decisions.

§ 9.4 Criteria.

(a) The official permitting use of Department facilities must determine that it would be consistent with the programs of his activity to participate. Facilities may be made available provided the use of such facilities will be of direct benefit to the objectives of the academic scientist, or engineer, or student, with the prospect of fruitful interchange of ideas and information between Department personnel and the academic scientist, or engineer, or student, and such use will not interfere with the Department program.

(b) The official permitting use of Department facilities will furnish the non-Government user with safety requirements or operating procedures to be followed. Such requirements or procedures are to include the requirement to report to the permitting official any accident involving the non-Government user.

(c) The official delegated authority for approving the use of Department facilities will not permit the use of laboratory facilities unless he determines:

(1) That facilities are available for the period desired; and

(2) That the proposed research will not interfere with regular Department functions or needs, nor require the subsequent acquisition of additional equipment by the Department.

§ 9.5 Restrictions.

(a) Each individual authorized to use Department facilities will be expected to use the facilities and equipment with customary care and otherwise conduct himself in such manner as to complete his research or study within any time limits prescribed.

(b) Each individual authorized to use HHS facilities may not be authorized to sign requisitions for supplies and equipment.

(c) Any official approving the use of HHS facilities should seek an agreement, executed by non-Government users, absolving the Federal agency of liability in case of personal injury, death, and failure or damage to the non-Government user's experiments or equipment. The agreement must also contain a statement that the non-Government user will comply with all safety regulations and procedures while using such facilities.

PART 11—COMMITTEE MANAGEMENT

Sec.
11.1 Scope.
11.2 Definitions.
11.3 General policies.
11.4 Guidelines for the creation and renewal of advisory committees.
11.5 Operation of advisory committees.
11.6 Administrative remedies.
11.7 Department committee management officer.

AUTHORITY: 86 Stat. 770, 5 U.S.C. App. I et seq. and Office of Management and Budget Circular A-63, 39 FR 12389, April 5, 1974.

SOURCE: 41 FR 35654, Aug. 23, 1976, unless otherwise noted.

§ 11.1 Scope.

(a) This part contains the Department's regulations implementing the Federal Advisory Committee Act.

(b) The regulations provided under this part apply to all advisory committees providing advice to the Department or any of its officials except to the extent that statutory provisions governing an advisory committee may specifically provide otherwise.

§ 11.2 Definitions.

(a) "Act" means the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770, 5 U.S.C. App. I et seq.).

(b) "Advisory committee," subject to exclusions described in paragraph (b)(3) of this section means any committee, board, commission, council, conference, panel, task force, or other similar group or any subcommittee or other subgroup thereof which is established by statute or reorganization plan; or established or utilized by the Department in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government.

(1) Although no single factor is determinative in deciding whether a

group is an advisory committee, the following factors will be considered:

(i) Fixed membership including at least one person who is not a full-time Federal employee;

(ii) Establishment by a Federal official or law; or if not federally established, the initiative for its use as an advisory body for the Federal Government comes from a Federal official rather than from a private group;

(iii) A purpose of providing advice regarding a particular subject or particular subjects;

(iv) An organizational structure (e.g.), officers and a staff;

(v) Regular or periodic meetings.

(2) The functions of an advisory committee are to be solely advisory. Where a group provides some advice to the Department, but the group's advisory function is incidental and inseparable from other (e.g., operational) functions, the provisions of this part do not apply. However, if the advisory function is separable, the group is subject to this part to the extent that the group operates as an advisory committee.

(3) Groups excluded from the effect of the provisions of this part include:

(i) Any committee which is composed wholly of full-time officers or employees of the Federal Government;

(ii) Any committee which is exclusively operational in nature (e.g., has functions which include making or implementing decisions, as opposed to the offerings of advice or recommendations);

(iii) Any local civic group whose primary function is that of rendering a public service with respect to a Federal program;

(iv) Any state or local committee or similar group established to advise State or local officials or agencies;

(v) The term "advisory committee" is not intended to include persons or organizations which have contractual relationships with the Department except in those cases where the criteria described in paragraph (b)(1) of this section are present:

(c) "Department" means the Department of Health and Human Services.

(d) "Secretary" means the Secretary of Health and Human Services, or his designee.

(e) "OMB Secretariat" is the office within the Office of Management and Budget to administer the provisions of OMB Circular A-63.

(f) "Presidential advisory committee" means an advisory committee which advises the President.

(g) "Statutory advisory committee" is one established by the Congress or required to be established by the Congress.

(h) "Non-statutory advisory committee" is one established by the President or other Federal officer, including a committee which was authorized by, but not established by or required to be established by statute.

§ 11.3 General policies.

(a) In interpreting this part, Department officials shall be guided by the Act and the intent of Congress in enacting the Act. These considerations include:

(1) Limiting the number of advisory committees to those that are essential and terminating any committee not fulfilling its purpose;

(2) Insuring effective use of advisory committees and their recommendations, while assuring that decisionmaking authority is retained by the responsible Department officers;

(3) Providing clear goals, standards and uniform procedures with respect to creation, operation, and duration of committees;

(4) Insuring that adequate information is provided to the President, the Congress and the public regarding advisory committees;

(5) Insuring adequate opportunities for access by the public to advisory committee meetings, and

(6) Providing uniform requirements for advisory committee reports and their availability to the public.

(b) Department officials shall be guided by the HHS Standards of Conduct (45 CFR 73.735), the Federal Personnel Manual, and the Federal Conflict of Interest statutes (18 U.S.C. 201 et seq.), in preventing conflicts of interest or appearance of conflicts of interest on the part of Department employees concerned with advisory committees, advisory committee members and staff, and consultants and experts concerned with advisory committees.

§ 11.4 Guidelines for the creation and renewal of advisory committees.

(a) Advisory committees shall be established by the Department only when they are determined to be essential. Their number shall be kept to the minimum necessary. They shall be terminated when they are no longer carrying out the purposes for which they were established or such purposes are no longer regarded as necessary to the operation of the department.

(b) No advisory committee shall be established or renewed unless such establishment or renewal is specifically authorized by statute, or established by statute or the President, or determined as a matter of formal record by the Secretary (after consultation with the OMB Secretariat) to be in the public interest in connection with the performance of duties imposed on the Department by law. In seeking such determination by the Secretary, the responsible official requesting establishment or continuance of an advisory committee shall make a request in writing to the Secretary. The request shall describe the nature or purpose of the proposed committee; the reasons why it is needed, including an explanation of why the functions of the proposed committee cannot be performed by Department employees, by an existing committee, or by some other means; and a description of the plan to attain balanced membership on the proposed committee in terms of the points of view to be represented, functions to be performed, and expected participation by women and minorities.

(c) No advisory committee shall meet or take any action until:

(1) In the case of establishment or renewal, in appropriate instances, the OMB Secretariat has been consulted.

(2) A formal charter has been approved by the Secretary;

(3) Public announcement of its establishment or renewal has been made in the FEDERAL REGISTER, at least fifteen days prior to the filing of the committee's charter.

(d) Copies of the charter shall be provided by the Department to the appropriate standing committees of the Senate and House of Representatives and to the Library of Congress. In the case of Presidential Committees a copy of the charter shall also be provided to the Office of Management and Budget. The charter shall be in a form prescribed by the Department Committee Management Officer and shall contain the following information:

(1) The committee's official designation;

(2) The committee's objectives and the scope of its activity;

(3) The period of time necessary for the committee to carry out its purpose;

(4) The official to whom the committee reports;

(5) The person responsible for providing the necessary support for the committee;

(6) A description of the duties for which the committee is responsible, and, if such duties are not solely advisory, a specification of the authority for such functions;

(7) The estimated annual operating costs in dollars and man-years for such committee;

(8) The estimated number and frequency of committee meetings;

(9) The committee's termination date, if less than two years from the date of the committee's establishment; and

(10) The date the charter is approved by the Secretary.

(e) With regard to subgroups, if all of its members are members of the parent committee, requisite information may be set forth in the charter of the parent committee. In the event a subgroup includes members who are not all drawn from the parent committee, it shall be separately chartered. In addition, if not incorporated in the charter of the parent committee, subgroups shall be separately chartered.

(f) No advisory committee shall be created if its functions could otherwise be performed effectively within the Department or by an existing committee.

(g) The membership of an advisory committee shall be fairly balanced in terms of the points of view represented and the committee's functions. Appropriate safeguards shall be taken to assure that an advisory committee's advice and recommendations will not be inappropriately influenced by any special interest, but shall instead be the result of the advisory committee's independent judgment.

(h) In the selection of committee members, there shall be no discrimination on the basis of race, color, national origin, religion, age, sex, or handicap.

(i) Each advisory committee shall prepare an annual report describing its membership, functions, recommendations and other actions. A copy of the report shall be submitted to the Department Committee Management Officer who shall make copies of them available to the public, upon request. In addition, a copy of the report shall be filed with the Department's Library and made available to the public. Notice of the availability of the Annual Report shall be published in the FEDERAL REGISTER no later than sixty days after its completion. Such notice shall indicate its availability to the public.

(j) Unless specifically provided otherwise by statute or Presidential directive, advisory committees shall be utilized solely for advisory functions. For purposes of this provision, "Presidential directive" refers to an executive order, executive memorandum or an OMB directive.

(k) Decisions regarding actions or policies relating to matters dealt with by a Department advisory committee hall be made solely by Department fficials.

(l) Except for committees created by Congress with a duration in excess of wo years, no Department advisory ommittee shall continue in existence or a period of more than two years rom its establishment unless renewed rior to the date of its scheduled termination by action of the Congress, he President, or the Secretary as appropriate. In the case of a committee ontinued by the Congress or the resident beyond its scheduled termiation date, a charter shall be aproved by the Secretary and the reuirements set forth in paragraph (c) of this section complied with before any meeting is held. To renew a committee the Secretary shall determine that such renewal is necessary and inform the OMB Secretariat of his determination and the reasons for it. Renewal determinations shall be made not more than sixty days before the scheduled date of termination. If the OMB Secretariat concurs, the Department Committee Management Officer shall notify the responsible Department officials who shall publish notice of the renewal in the FEDERAL REGISTER. A new charter shall also be approved by the Secretary.

(m) Any advisory committee which is renewed may continue for no more than a two-year period unless prior to the expiration of that period it is renewed for another two-year period in accord with the above provisions.

§ 11.5 Operation of advisory committees.

(a) *Meetings.* The provisions of this section shall apply to meetings of all Department advisory committees and all subgroups.

(1) *Calling of meetings and agenda.* (i) No advisory committee shall hold any meetings except at the call of or with the advance approval of the designated Department official.

(ii) No meeting shall be held in the absence of a quorum. Unless otherwise established in the charter of the committee, a quorum shall consist of a majority of the committee's authorized membership, including ex officio members. In addition, such members shall have full voting rights.

(iii) Each meeting of an advisory committee shall be conducted in accordance with an agenda approved by the designated Department official. Ordinarily, copies of the agenda shall be distributed to the members of the committee prior to the date of the meeting. The agenda shall list the matters to be considered at the meeting and shall indicate whether any part of the meeting is concerned with matters which are within the exemptions of the Freedom of Information Act, 5 U.S.C. 552(b).

(2) *Notice of meeting.* (i) Except when the Director of the Office of Management and Budget determines

otherwise for reasons of national security, or except as otherwise provided herein, notice of each advisory committee meeting shall be published in the Federal Register at least fifteen days prior to the meeting. The fact that a meeting is closed to the public pursuant to paragraph 10(d) of Pub. L. 92-463 shall not affect the foregoing requirement.

(*a*) The notice shall state the name of the advisory committee, the time and place of the meeting, and the purposes of the meeting and shall include a summary of the agenda.

(*b*) The notice shall state the extent to which the public will be permitted to attend or participate in the meeting. If the meeting will be closed to the public, the notice shall also state the reasons for closing, including appropriate citation to the Freedom of Information Act.

(ii) In addition to notice in the Federal Register, the Executive Secretary of each advisory committee shall maintain a list of persons and organizations who have requested to be notified of all meetings and notify them by mail in advance of any meeting. Other forms of notice, such as press releases and notices in professional journals shall be used to the extent practicable.

(iii) Meetings may be held only in emergency situations unless notice of the meeting has been published in the Federal Register at least fifteen days prior to the meeting. Such meetings shall be kept to a minimum, and whenever feasible, rescheduled for a later date. When a meeting must be called without fifteen days notice being given, the following steps shall be taken, to the extent possible:

(*a*) Advance notice shall be published in the Federal Register.

(*b*) Other forms of notice shall be utilized whenever practicable.

(*c*) In the case of meeting notices published in accordance with paragraphs (a)(2)(iii) (*a*) and (*b*) of this section, the notice shall contain an explanation for the failure to give fifteen days notice.

(3) *Public participation at meetings.* (i) Subject to the exceptions described in paragraph (a)(6) of this section each advisory committee meeting shall be open to the public, and interested persons shall be permitted to attend, appear before, or file statements with any advisory committee.

(ii) The Executive Secretary of each committee shall, with respect to any advisory committee meeting, all or part of which is open to the public, assure compliance with the following rules:

(*a*) Meetings shall be held at reasonable times and places that are reasonably accessible to members of the public. Whenever feasible, Government facilities shall be used and meetings held in places involving the least expense to the Department.

(*b*) The size of the meeting room shall be reasonable, considering such factors as the size of the advisory committee, the number of members of the public expected to seek to attend, and the resources and facilities available to the Department.

(*c*) Any member of the public who wishes to do so shall be permitted to file a written statement with the committee, before or after a meeting.

(*d*) To the extent that the time available for a meeting permits, interested persons may be permitted to present oral statements. Any person seeking to present an oral statement to a committee may be required to obtain advance approval for such participation from the committee chairman or the committee's Executive Secretary.

(*e*) Participation by members of the public at committee meetings or questioning of committee members or other participants shall only be permitted with the authorization of the committee chairman.

(4) *Minutes and transcripts of meetings.* (i) Detailed minutes shall be kept of each meeting of each advisory committee, including meetings of formal and informal subgroups. The Executive Secretary of each advisory committee shall keep the minutes or designate some person to keep the minutes. Minutes need not be kept if a verbatim transcript is made.

(ii) The minutes shall include at least the following: The time and place of the meeting; a list of advisory committee members and staff and full-time Federal employees present at the meeting; a detailed summary of matters discussed, including different positions advanced by members and conclusions reached by the committee; copies of all reports received, issued, or approved by the advisory committee; an explanation of the extent to which the meeting was open to the public; and explanation of the extent of public participation, including a list of members of the public who presented oral or written statements; and an estimate of the number of members of the public who attended the meeting.

(iii) Within a reasonable time after the meeting the minutes shall be completed and submitted to the chairman of the advisory committee.

(iv) Within a reasonable time after receipt of the minutes the chairman of the advisory committee shall certify to the accuracy of the minutes and submit them to the Executive Secretary for submission to the official advised by the committee.

(5) *Designated Department employee.* (i) Each advisory committee meeting shall be attended by a Department employee designated by the Department official responsible for the Committee. Ordinarily, the employee so designated shall serve the advisory committee on a continuing basis.

(ii) No advisory committee shall conduct a meeting in the absence of the designated Department employee. If simultaneous subgroup meetings are to be held, each subgroup shall have a designated Department employee in attendance.

(iii) The designated Department employee is authorized to adjourn any advisory committee meeting, whenever he determines adjournment to be in the public interest. Inter alia, the designated Department employee shall adjourn the meeting in the event of unwarranted departure from a meeting's agenda.

(6) *Closing advisory committee meetings.* (i) Subsection 10(d) of the Act provides that the provisions concerning open meetings and public participation shall not apply to any advisory committee which the President, or the head of the department to which the advisory committee reports, determines is concerned with matters listed in 5 U.S.C. 552(b). The Department's regulation implementing that Act is found at 45 CFR Part 5. Department officials shall be guided by the policies set forth in that regulation in making determinations to close meetings. In applying the provisions of 5 U.S.C. 552(b) to advisory committee meetings, liberal interpretations shall be assumed with respect to the openness of such meetings. Any determination to close a meeting (or portion) shall restrict such closing to the shortest reasonable time.

(ii) In applying the Freedom of Information Act exemptions to advisory committee meetings, the following rules shall be followed:

(*a*) If a meeting (or portion) will have the express purposes of discussing an existing document which is within one of the exemptions set forth in 5 U.S.C. 552(b), the meeting (or portion) may be closed to the public.

(*b*) Meetings closed solely on the basis that a document exempt from mandatory disclosure under exemption (5) (concerning intra-agency and inter-agency memoranda and letters) is to be discussed, may only be closed if the Secretary determines that it is essential to close such meeting (or portion) to protect the free exchange of internal views of committee members and avoid undue interference with Department or committee operation.

(*c*) A meeting (or portion) involving solely the internal expression of views and judgments of committee members, and not the discussion of an exempt document may be closed if a finding is made that is essential to close the meeting (or portion) to protect the free exchange of members views and avoid undue interference with Department or committee operations, and such views if reduced to writing would be protected from mandatory disclosure under section 552(b)(5) of Title 5 U.S.C. When feasible, the public shall be given an opportunity to present relevant information and views to the committee. Concurrence for closing such a meeting shall be obtained from the Office of the General Counsel and the Office of Public Affairs.

(*d*) If a meeting (or portion) will have the express purpose of discussing a matter which is within one of the exemptions set forth in 5 U.S.C. 552(b), other than exemption (5), the meeting (or portion) may be closed to the public even though no specific exempt document is to be discussed.

(*e*) If the subject of a meeting will be such that paragraphs (a)(6)(ii) (*a*) through (*d*) inclusive above do not furnish a basis for closing it, the meeting shall be open to the public.

(*f*) When a advisory committee seeks to have a meeting (or portion) closed, the Executive Secretary shall make a request in writing for a determination by the Secretary. Such a request shall set forth the reasons why the meeting (or portion) should be closed. Whenever practical, the request shall be submitted at least sixty days before the scheduled date of the meeting.

(*g*) If the Secretary finds the request to be warranted and in accord with the policy of the Act and the Freedom of Information Act, the request shall be granted. The determination made by the Secretary shall be in writing and contain specific reasons for closing the meeting (or portion). Determinations made by authorized designees must be reviewed and approved by the Office of the General Counsel and the Office of Public Affairs.

(*h*) If a meeting is to be held for the consideration of several separable matters, not all of which are within the exemptions of 5 U.S.C. 552(b), only the portion of the meeting dealing with exempt matters may be closed.

(*i*) When part of a meeting is to be closed, the agenda shall be arranged to facilitate attendance by the public at the open portion of the meeting.

(*j*) When a meeting (or portion) is closed, only members of the committee, its staff, and Federal employees shall be permitted to attend.

(*k*) When a meeting (or portion) is closed, members of the advisory committee shall not disclose the matters discussed except to other members of the advisory committee, the staff of the advisory committee or Department employees.

(*l*) The Department Committee Management Officer may review, after the meeting, the appropriateness of any determination to close a meeting (or portion) and require that corrective action be taken with respect to the particular advisory committee or general procedures concerning the closing of meetings.

(*m*) When a meeting (or portion) is closed, and detailed minutes are not to be made available in their entirety to the public, the advisory committee shall prepare and make available to the public within fourteen days of the close of the meeting a summary of its activities and related matters which are informative to the public consistent with the policy of 5 U.S.C. 552(b). Notice of the availability of such a summary shall be incorporated in the notice of the meeting published in the FEDERAL REGISTER.

(b) *Access to records.* (1) All records, reports, and other documents of each advisory committee shall be available for public inspection and copying pursuant to the Department's public information regulation. Documents referred to herein include the records, reports, transcripts, minutes, appendices, working papers, drafts, studies, agenda or other documents which were made available to or prepared for or by each advisory committee.

(2) Advisory committee records determined to be available for public inspection are to be made available for inspection and copying at a single location in the offices of the advisory committee or the Department organizational component to which the advisory committee reports. The advisory committee or appropriate Department organizational component shall make available to any person copies of transcripts of committee proceedings or meetings at cost determined in accordance with the appropriate fee schedule.

(3) Advisory committee records are maintained and disposed of according to procedures prescribed in the Department's Records Management Manual.

§ 11.6 Administrative remedies.

(a) Any person whose request for access to an advisory committee document is denied may seek administrative review in accord with the Department's Freedom of Information Act regulation.

(b) Any person whose request for access to an advisory committee meeting is denied after publication of the notice of the meeting in the FEDERAL REGISTER may appeal to the appropriate official designated at 45 CFR 5.82. If the decision on appeal is adverse to the request or concurrence of the Assistant Secretary for Public Affairs or his designee, shall be obtained.

§ 11.7 Department committee management officer.

The Secretary shall designate a Department employee to implement this part and consult with the Office of Management and Budget on his behalf.

PART 12—DISPOSAL AND UTILIZATION OF SURPLUS REAL PROPERTY FOR PUBLIC HEALTH PURPOSES

Sec.

12.1 Definitions.
12.2 Scope.
12.3 General policies.
12.4 Limitations.
12.5 Awards.
12.6 Notice of available property.
12.7 Applications for surplus real property.
12.8 Assignment of surplus real property.
12.9 General disposal terms and conditions.
12.10 Compliance with the National Environmental Policy Act of 1969 and other related Acts (environmental impact).
12.11 Special terms and conditions.
12.12 Utilization.
12.13 Form of conveyance.
12.14 Compliance inspections and reports.
12.15 Reports to Congress.
EXHIBIT A—PUBLIC BENEFIT ALLOWANCE FOR TRANSFER OF REAL PROPERTY FOR HEALTH PURPOSES

AUTHORITY: Sec. 203, 63 Stat. 385, as amended; 40 U.S.C. 484; sec. 501 of Pub. L. 100-77, 101 Stat. 509-10, 42 U.S.C. 11411.

SOURCE: 45 FR 72173, Oct. 31, 1980, unless otherwise noted.

§ 12.1 Definitions.

(a) "Act" means the Federal Property and Administrative Services Act of 1949, 63 Stat. 377 (40 U.S.C. 471 et seq.). Terms defined in the Act and not defined in this section have the meanings given to them in the Act.

(b) "Accredited" means having the approval of a recognized accreditation board or association on a regional, State, or national level, such as a State Board of Health. "Approval" as used above describes the formal process carried out by State Agencies and institutions in determining that health organizations or programs meet minimum acceptance standards.

(c) "Administrator" means the Administrator of General Services.

(d) "Assigned property" means real and related personal property which, in the discretion of the Administrator or his designee, has been made available to the Department for transfer for public health purposes.

(e) "Department" means the U.S. Department of Health and Human Services.

(f) "Disposal agency" means the executive agency of the Government which has authority to assign property to the Department for transfer for public health purposes.

(g) "Excess" means any property under the control of any Federal agency which is not required for its needs and the discharge of its responsibilities, as determined by the head thereof.

(h) "Fair market value" means the highest price which the property will bring by sale in the open market by a willing seller to a willing buyer.

(i) "Holding agency" means the Federal agency which has control over and accountability for the property involved.

(j) "Nonprofit institution" means any institution, organization, or association, whether incorporated or unincorporated, no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual, and (except for institutions which lease property to assist the homeless under Title V of Pub. L. 100-77) which has been held to be tax-exempt under section 501(c)(3) of the Internal Revenue Code of 1954.

(k) "Off-site property" means surplus buildings, utilities and all other removable improvements, including related personal property, to be transferred by the Department for removal and use away from the site for public health purposes.

(l) "On-site" means surplus real property, including related personal property, to be transferred by the Department for use in place for public health purposes.

(m) "Public benefit allowance" means a discount on the sale or lease price of real property transferred for public health purposes, representing any benefit determined by the Secretary which has accrued or may accrue to the United States thereby.

(n) "Related personal property" means any personal property: (1) Which is located on and is (i) an integral part of, or (ii) useful in the operation of real property; or (2) which is determined by the Administrator to be otherwise related to the real property.

(o) "Secretary" means the Secretary of Health and Human Services.

(p) "State" means a State of the United States, and includes the District of Columbia, the Commonwealth of Puerto Rico, and the Territories and possessions of the United States.

(q) "Surplus" when used with respect to real property means any excess real property not required for the needs and the discharge of the responsibilities of all Federal agencies as determined by the Administrator.

[45 FR 72173, Oct. 31, 1980, as amended at 53 FR 7745, Mar. 10, 1988]

§ 12.2 Scope.

This part is applicable to surplus real property located within any State which is appropriate for assignment to, or which has been assigned to, the Department for transfer for public health purposes, as provided for in section 203(k) of the Act.

§ 12.3 General policies.

(a) It is the policy of the Department to foster and assure maximum utilization of surplus real property for public health purposes, including research.

(b) Transfers may be made only to States, their political subdivisions and instrumentalities, tax-supported public health institutions, and nonprofit public health institutions which (except for institutions which lease property to assist the homeless under Title V of Pub. L. 100-77) have been held tax-exempt under section 501(c)(3) of the Internal Revenue Code of 1954.

(c) Real property will be requested for assignment only when the Department has determined that the property is suitable and needed for public health purposes. The amount of real and related personal property to be transferred shall not exceed normal operating requirements of the applicant. Such property will not be requested for assignment unless it is needed at the time of application for public health purposes or will be so needed within the immediate or foreseeable future. Where construction or major renovation is not required or proposed, the property must be placed into use within twelve (12) months from the date of transfer. When construction or major renovation is contemplated at the time of transfer, the property must be placed in use within 36 months from the date of transfer. If the applicable time limitation is not met, the transferee shall either commence payments in cash to the Department for each month thereafter during which the proposed use has not been implemented or take such other action as set forth in § 12.12 as is deemed appropriate by the Department. Such monthly payments shall be computed on the basis of the current fair market value of the property at the time of the first payment by subtracting therefrom any portion of the purchase price paid in cash at the time of transfer, and by dividing the balance by the total number of months in the period of restriction. If the facility has not been placed into use within eight (8) years of the date of the deed, title to the property will be revested in the United States, or, at the discretion of the Department, the restrictions and conditions may be abrogated in accordance with § 12.9.

(d) Transfers will be made only after the applicant has certified that the proposed program is not in conflict with State or local zoning restrictions, building codes, or similar limitations.

(e) Organizations which may be eligible include those which provide care and training for the physically and mentally ill, including medical care of the aged and infirm; clinical services; services (including shelter) to homeless individuals; other public health services (including water and sewer); or similar services devoted primarily to the promotion and protection of public health. In addition, organizations which provide assistance to homeless individuals may be eligible for leases under title V of Public Law 100-77. Except for the provision of services (including shelter) to homeless individuals, organizations which have as their principal purpose the providing of custodial or domiciliary care are not eligible. The eligible organization must be authorized to carry out the activity for which it requests the property.

(f) An applicant's plan of operation will not be approved unless it provides that the applicant will not discriminate because of race, color, sex, handicap, or national origin in the use of the property.

[45 FR 72173, Oct. 31, 1980, as amended at 53 FR 7745, Mar. 10, 1988; 55 FR 32252, Aug. 8, 1990]

§ 12.4 Limitations.

(a) Surplus property transferred pursuant to this part will be disposed of on an "as is, where is," basis without warranty of any kind.

(b) Unless excepted by the General Services Administrator in his assignment, mineral rights will be conveyed together with the surface rights.

§ 12.5 Awards.

Where there is more than one applicant for the same property, it will be awarded to the applicant having a program of utilization which provides, in the opinion of the Department, the greatest public benefit. Where the property will serve more than one program, it will be apportioned to fit the needs of as many programs as is practicable.

§ 12.6 Notice of available property.

Reasonable publicity will be given to the availability of surplus real property which is suitable for assignment to the Department for transfer for public health uses. The Department will establish procedures reasonably calculated to afford all eligible users having a legitimate interest in acquiring the property for such uses an opportunity to make an application therefor. However, publicity need not be given to the availability of surplus real property which is occupied and being used for eligible public health purposes at the time the property is declared surplus, the occupant expresses interest in the property, and the Department determines that it has a continuing need therefor.

§ 12.7 Applications for surplus real property.

Applications for surplus real property for public health purposes shall be made to the Department through the office specified in the notice of availability.

[55 FR 32252, Aug. 8, 1990]

§ 12.8 Assignment of surplus real property.

(a) Notice of interest in a specific property for public health purposes will be furnished the General Services Administrator by the Department at the earliest possible date.

(b) Requests to the Administrator for assignment of surplus real property to the Department for transfer for public health purposes will be based on the following conditions:

(1) The Department has an acceptable application for the property.

(2) The applicant is willing, authorized, and in a position to assume immediate care, custody, and maintenance of the property.

(3) The applicant is able, willing and authorized to pay the administrative expenses incident to the transfer.

(4) The applicant has the necessary funds, or the ability to obtain such funds, to carry out the approved program of use of the property.

§ 12.9 General disposal terms and conditions.

(a) Surplus real property transfers under this part will be limited to public health purposes. Transferees shall be entitled to a public benefit allowance in terms of a percentage which will be applied against the value of the property to be conveyed. Such an allowance will be computed on the basis of benefits to the United States from the use of such property for public health purposes. The computation of such public benefit allowances will be in accordance with Exhibit A attached hereto and made a part hereof.

(b) A transfer of surplus real property for public health purposes is subject to the disapproval of the Administrator within 30 days after notice is given to him of the proposed transfer.

(c) Transfers will be on the following terms and conditions:

(1) The transferee will be obligated to utilize the property continuously in accordance with an approved plan of operation.

(2) The transferee will not be permitted to sell, lease or sublease, rent, mortgage, encumber, or otherwise dispose of the property, or any part thereof, without the prior written authorization of the Department.

(3) The transferee will file with the Department such reports covering the utilization of the property as may be required.

(4) In the event the property is sold, leased or subleased, encumbered, disposed of, or is used for purposes other than those set forth in the approved plan without the consent of the Department, all revenues or the reasonable value of other benefits received by the transferee directly or indirectly from such use, as determined by the Department, will be considered to have been received and held in trust by the transferee for the account of the United States and will be subject to the direction and control of the Department. The provisions of this paragraph shall not impair or affect the rights reserved to the United States in paragraph (c)(6) of this section, or the right of the Department to impose conditions to its consent.

(5) Lessees will be required to carry all perils and liability insurance to protect the Government and the Government's residual interest in the property. Transferees will be required to carry such flood insurance as may be required by the Department pursuant to Pub. L. 93-234. Where the transferee elects to carry insurance against damages to or loss of on-site property due to fire or other hazards, and where loss or damage to transferred Federal surplus real property occurs, all proceeds from insurance shall be promptly used by the transferee for the purpose of repairing and restoring the property to its former condition, or replacing it with equivalent or more suitable facilities. If not so used, there shall be paid to the United States that part of the insurance proceeds that is attributable to the Government's residual interest in the property lost, damaged, or destroyed in the case of leases, attributable to the fair market value of the leased facilities.

(6) With respect to on-site property, in the event of noncompliance with any of the conditions of the transfer as determined by the Department, title to the property transferred and the right to immediate possession shall, at the option of the Department, revert to the Government. In the event title is reverted to the United States for noncompliance or voluntarily reconveyed, the transferee shall, at the option of the Department, be required to reimburse the Government for the decrease in value of the property not due to reasonable wear and tear or acts of God or attributable to alterations completed by the transferee to adapt the property to the public health use for which the property was transferred. With respect to leased property, in the event of noncompliance with any of the conditions of the lease, as determined by the Department, the right of occupancy and possession shall, at the option of the Department, be terminated. In the event a leasehold is terminated by the United States for noncompliance or is voluntarily surrendered, the lessee shall be required at the option of the Department to reimburse the Government for the decrease in value of the property not due to reasonable wear and tear or acts of God or attributable to alterations completed by the lessee to adapt the property to the public health use for which the property was leased.

With respect to any reverter of title or termination of leasehold resulting from noncompliance, the Government shall, in addition thereto, be reimbursed for such costs as may be incurred in recovering title to or possession of the property.

Any payments of cash made by the transferee against the purchase price of property transferred shall, upon a forfeiture of title to the property for breach of condition, be forfeited.

(7) With respect to off-site property, in the event of noncompliance with any of the terms and conditions of the transfer, the unearned public benefit allowance shall, at the option of the Department, become immediately due and payable or, if the property or any portion thereof is sold, leased, or otherwise disposed of without authorization from the Department, such sale, lease or sublease, or other disposal shall be for the benefit and account of the United States and the United States shall be entitled to the proceeds. In the event the transferee fails to remove the property or any portion thereof within the time specified, then in addition to the rights reserved above, at the option of the Department, all right, title, and interest in and to such unremoved property shall be retransferred to other eligible applicants or shall be forfeited to the United States.

(8) With respect only to on-site property which has been declared excess by the Department of Defense, such declaration having included a statement indicating the property has a known potential for use during a national emergency, the Department shall reserve the right during any period of emergency declared by the President of the United States or by the Congress of the United States to the full and unrestricted use by the Government of the surplus real property, or of any portion thereof, disposed of in accordance with the provisions of this part. Such use may be either exclusive or nonexclusive. Prior to the expiration or termination of the period of restricted use by the transferee, the Government will not be obligated to pay rent or any other fees or charges during the period of emergency, except that the Government will:

(i) Bear the entire cost of maintenance of such portion of the property used by it exclusively or over which it may have exclusive possession or control;

(ii) Pay the fair share, commensurate with the use of the cost of maintenance of such surplus real property as it may use nonexclusively or over which it may have nonexclusive possession or control;

(iii) Pay a fair rental for the use of improvements or additions to the surplus real property made by the purchaser or lessee without Government aid; and

(iv) Be responsible for any damage to the surplus real property caused by its use, reasonable wear and tear, the common enemy and acts of God excepted. Subsequent to the expiration or termination of the period of restricted use, the obligations of the Government will be as set forth in the preceding sentence and, in addition, the Government shall be obligated to pay a fair rental for all or any portion of the conveyed premises which it uses.

(9) The restrictions set forth in paragraphs (c) (1) through (7) of this section will extend for thirty (30) years for land with or without improvements; and for facilities being acquired separately from land whether they are for use on-site or off-site, the period of limitations on the use of the structures will be equal to their estimated economic life. The restrictions set forth in paragraphs (c) (1) through (7) of this section will extend for the entire initial lease period and for any renewal periods for property leased from the Department.

(d) Transferees, by obtaining the consent of the Department, may abrogate the restrictions set forth in paragraph (c) of this section for all or any portion of the property upon payment in cash to the Department of an amount equal to the then current fair market value of the property to be released, multiplied by the public benefit allowance granted at the time of conveyance, divided by the total number of months of the period of restriction set forth in the conveyance document and multiplied by the number of months that remain in the period of restriction as determined by the Department. For purposes of abrogation payment computation, the current fair market value shall not include the value of any improvements placed on the property by the transferee.

(e) Related personal property will be transferred or leased as a part of the realty and in accordance with real property procedures. It will be subject to the same public benefit allowance granted for the real property. Where related personal property is involved in an on-site transfer, the related personal property may be transferred by a bill of sale imposing restrictions for a period not to exceed five years from the date of transfer, other terms and conditions to be the same as, and made a part of, the real property transaction.

§ 12.10 Compliance with the National Environmental Policy Act of 1969 and other related acts (environmental impact).

(a) The Department will, prior to making a final decision to convey or lease, or to amend, reform, or grant an approval or release with respect to a previous conveyance or lease of, surplus real property for public health purposes, complete an environmental assessment of the proposed transaction in keeping with applicable provisions of the National Environmental Policy Act of 1969, the National Historic Preservation Act of 1966, the National Archeological Data Preservation Act, and other related acts. No permit to use surplus real property shall allow the permittee to make, or cause to be made, any irreversible change in the condition of said property, and no use permit shall be employed for the purpose of delaying or avoiding compliance with the requirements of these Acts.

(b) Applicants shall be required to provide such information as the Department deems necessary to make an assessment of the impact of the proposed Federal action on the human environment. Materials contained in the applicant's official request, responses to a standard questionnaire prescribed by the Public Health Service, as well as other relevant information, will be used by the Department in making said assessment.

(c) If the assessment reveals (1) That the proposed Federal action involves properties of historical significance which are listed, or eligible for listing, in the National Register of Historic Places, or (2) that a more than insignificant impact on the human environment is reasonably foreseeable
a result of the proposed action, or (
that the proposed Federal action cou
result in irreparable loss or destru
tion of archeologically significa
items or data, the Department wi
except as provided for in paragrap
(d) of this section, prepare and distri
ute, or cause to be prepared or distri
uted, such notices and statements an
obtain such approvals as are require
by the above cited Acts.

(d) If a proposed action involve
other Federal agencies in a sequenc
of actions, or a group of actions, d
rectly related to each other because o
their functional interdependence, th
Department may enter into and sup
port a lead agency agreement to desig
nate a single lead agency which wi
assume primary responsibility for co
ordinating the assessment of environ
mental effects of proposed Federal ac
tions, preparing and distributing such
notices and statements, or obtainin
such approvals, as are required by th
above cited Acts. The procedures o
the designated lead agency will be utilized in conducting the environmental assessment. In the event of disagreement between the Department and another Federal agency, the Department will reserve the right to abrogate its lead agency agreement with the other Federal Agency.

[45 FR 72173, Oct. 31, 1980, as amended at 55 FR 32252, Aug. 8, 1990]

§ 12.11 Special terms and conditions.

(a) Applicants will be required to pay all external administrative costs which will include, but not be limited to, taxes, surveys, appraisals, inventory costs, legal fees, title search, certificate or abstract expenses, decontamination costs, moving costs, closing fees in connection with the transaction and service charges, if any, made by State Agencies for Federal Property Assistance under the terms of a cooperative agreement with the Department.

(b) In the case of off-site property, applicants will be required to post performance bonds, make performance guarantee deposits, or give such other assurances as may be required by the Department or the holding agency to insure adequate site clearance and to pay service charges, if any, made by State Agencies for Federal Property Assistance under the terms of a cooperative agreement with the Department.

(c) Whenever negotiations are undertaken for disposal to private nonprofit public health organizations of any surplus real property which cost the Government $1 million or more, the Department will give notice to the Attorney General of the United States of the proposed disposal and the terms and conditions thereof. The applicant shall furnish to the Department such information and documents as the Attorney General may determine to be appropriate or necessary to enable him to give the advice as provided for by section 207 of the Act.

(d) Where an applicant proposes to acquire or lease and use in place improvements located on land which the Government does not own, he shall be required, before the transfer is consummated, to obtain a right to use the land commensurate with the duration of the restrictions applicable to the improvements, or the term of the lease. The applicant will be required to assume, or obtain release of, the Government's obligations respecting the land including but not limited to obligations relating to restoration, waste, and rent. At the option of the Department, the applicant may be required to post a bond to indemnify the Government against such obligations.

(e) The Department may require the inclusion in the transfer or lease document of any other provision deemed desirable or necessary.

(f) Where an eligible applicant for an on-site transfer proposes to construct new, or rehabilitate old, facilities, the financing of which must be accomplished through issuance of revenue bonds having terms inconsistent with the terms and conditions of transfer prescribed in § 12.9 (c), (d), and (e) of this chapter, the Department may, in its discretion, impose such alternate terms and conditions of transfer in lieu thereof as may be appropriate to assure utilization of the property for public health purposes.

§ 12.12 Utilization.

(a) Where property or any portion thereof is not being used for the purposes for which transferred, the transferee will be required at the direction of the Department:

(1) To place the property into immediate use for an approved purpose;

(2) To retransfer such property to such other public health user as the Department may direct;

(3) To sell such property for the benefit and account of the United States;

(4) To return title to such property to the United States or to relinquish any leasehold interest therein;

(5) To abrogate the conditions and restrictions of the transfer, as set forth in § 12.9(d) of this chapter, except that, where property has never been placed in use for the purposes for which transferred, abrogation will not be permitted except under extenuating circumstances; or

(6) To make payments as provided for in § 12.3(c) of this chapter.

(b) Where the transferee or lessee desires to place the property in temporary use for a purpose other than that for which the property was transferred or leased, approval from the Department must be obtained, and will be conditioned upon such terms as the Department may impose.

§ 12.13 Form of conveyance.

(a) Transfers or leases of surplus real property will be on forms approved by the Office of General Counsel of the Department and will include such of the disposal or lease terms and conditions set forth in this part and such other terms and conditions as the Office of General Counsel may deem appropriate or necessary.

(b) Transfers of on-site property will normally be by quitclaim deed without warranty of title.

§ 12.14 Compliance inspections and reports.

The Department will make or have made such compliance inspections as are necessary and will require of the transferee or lessee such compliance reports and actions as are deemed necessary.

§ 12.15 Reports to Congress.

The Secretary will make such reports of real property disposal activities as are required by section 203 of the Act and such other reports as may be required by law.

EXHIBIT A—PUBLIC BENEFIT ALLOWANCE FOR TRANSFER OF REAL PROPERTY FOR HEALTH PURPOSES [1]

Classification	Percent allowed											
	Organization allowances							Utilization allowances				Maximum public benefit allowance
	Basic public benefit allowance	Tax support	Accreditation	Hardship	Unmet needs			Integrated research program	Outpatient services	Public services	Training program	
					10 to 25%	26 to 50%	51 to 100%					
Hospitals	50	20	20	10	10	20	30	10	10	10	10	100
Clinics	50	20	20	10	10	20	30					100
Nursing Homes	50	20	20	10	10	20	30				10	100
Public Health Administration	[2] 100											[2] 100
Public Refuse Disposal and Water Systems	[2] 100											[2] 100
Research	[2] 100											[2] 100
Rehabilitation Facility	50	20	20	10	10	20	30	10	10	10	10	100
Special Services	50	20	20	10	10	20	30			10		100
Assistance to the Homeless	[2] 100											[2] 100

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[1] This public benefit allowance applies only to surplus real property being sold for on-site use. When surplus real property is to be moved from the site, a basic public benefit allowance of 100% will be granted.

[2] Applicable when this is the primary use to be made of the property. The public benefit allowance for the overall health program is applicable when such facilities are conveyed as a minor component of other facilities.

[45 FR 72173, Oct. 31, 1980, as amended at 53 FR 7745, Mar. 10, 1988]

PART 13—IMPLEMENTATION OF THE EQUAL ACCESS TO JUSTICE ACT IN AGENCY PROCEEDINGS

Subpart A—General Provisions

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APPENDIX A

AUTHORITY: Sec. 203(a)(1), Pub. L. 96-481, 94 Stat. 2325 (5 U.S.C. 504(c)(1)).

SOURCE: 48 FR 45252, Oct. 4, 1983, unless otherwise noted.

Subpart A—General Provisions

§ 13.1 Purpose of these rules.

These rules implement section 203 of the Equal Access to Justice Act, 5 U.S.C. 504 and 504 note, for the Department of Health and Human Services. They describe the circumstances under which the Department may award attorney fees and certain other expenses to eligible individuals and entities who prevail over the Department in certain administrative proceedings (called "adversary adjudications"). The Department may reimburse parties for expenses incurred in adversary adjudications if the party prevails in the proceeding and if the Department's position in the proceeding was not substantially justified. These rules explain how to apply for an award. They also describe what proceedings constitute adversary adjudications covered by the Act, what types of persons and entities may be eligible for an award, and what procedures and standards the Department will use to make a determination as to whether a party may receive an award.

§ 13.2 When these rules apply.

These rules apply to adversary adjudications pending before the Department between October 1, 1981 and September 30, 1984.

§ 13.3 Proceedings covered.

(a) These rules apply only to adversary adjudications. For the purpose of these rules, only an adjudication required to be under 5 U.S.C. 554, in which the position of the Department or one of its components is represented by an attorney or other representative ("the agency's litigating party") who enters an appearance and participates in the proceeding, constitutes an adversary adjudication. These rules do not apply to proceedings for the purpose of establishing or fixing a rate or for the purpose of granting, denying, or renewing a license. Department proceedings covered by these rules, if the agency's litigating party enters an appearance and participates, are listed in Appendix A.

(b) If a proceeding is covered by these rules, but also involves issues excluded under paragraph (a) of this section from the coverage of these rules, reimbursement is available only for fees and expenses resulting from covered issues.

§ 13.4 Eligibility of applicants.

(a) To be eligible for an award of attorney fees and other expenses under these regulations, the applicant must be a party, as defined in 5 U.S.C. 551(3), to the adversary adjudication for which it seeks an award. An applicant must show that it meets all conditions of eligibility set out in this subpart and in Subpart B.

(b) The categories of eligible applicants are as follows:

(1) Individuals with a net worth of not more than $1 million;

(2) Sole owners of unincorporated businesses if the owner has a net worth of not more than $5 million, including both personal and business interests, and not more than 500 employees;

(3) Charitable or other tax-exempt organizations described in section 501(c)(3) of the Internal Revenue Code (26 U.S.C. 501(c)(3)) with not more than 500 employees;

(4) Cooperative associations as defined in section 15(a) of the Agricultural Marketing Act (12 U.S.C. 1141j(a)) with not more than 500 employees, and

(5) All other partnerships, corporations, associations or public or private organizations with a net worth of not more than $5 million and with not more than 500 employees.

(c) For the purpose of determining eligibility, the net worth and number of employees of an applicant is calculated as of the date the proceeding was initiated. The net worth of an applicant is determined by generally accepted accounting principles.

(d) Whether an applicant who owns an unincorporated business will be considered as an "individual" or a "sole owner of an unincorporated business" will be determined by whether the applicant's participation in the proceeding is related primarily to individual interests or to business interests.

(e) The employees of an applicant include all those persons regularly providing services for remuneration for the applicant, under the applicant's direction and control. Part-time employees shall be included on a proportional basis.

(f) The net worth and number of employees of the applicant and all of its affiliates shall be aggregated to determine eligibility. Any individual, corporation or other entity that directly or indirectly controls or owns a majority of the voting shares or other interest of the applicant, or any corporation or other entity of which the applicant directly or indirectly owns or controls a majority of the voting shares or other interest, will be considered an affiliate for purposes of this part, unless the adjudicative officer determines that such treatment would be unjust and contrary to the purposes of the Act in light of the actual relationship between the affiliated entities. In addition, the adjudicative officer may determine that financial relationships of the applicant other than those described in this paragraph constitute special circumstances that would make an award unjust.

(g) An applicant is not eligible if it appears from the facts and circumstances that it has participated in the proceedings only or primarily on behalf of other persons or entities that are ineligible.

§ 13.5 Standards for awards.

(a) Awards will not be made for fees and expenses where the Department's position in the proceeding was substantially justified at the time the proceeding was initiated. The fact that a party has prevailed in a proceeding does not create a presumption that the Department's position was not substantially justified. The burden of proof that an award should not be made to an eligible prevailing applicant is on the agency's litigating party, which may avoid an award by showing that its position was reasonable in law and fact.

(b) When two or more matters are joined together for one hearing, each of which could have been heard separately (without regard to laws or rules fixing a jurisdictional minimum amount for claims), and an applicant has prevailed with respect to one or several of the matters, an eligible applicant may receive an award for expenses associated only with the matters on which it prevailed if the Department's position on those matters was not substantially justified.

(c) Awards for fees and expenses incurred before the date on which a proceeding was initiated will be made only if the applicant can demonstrate that they were reasonably incurred in preparation for the proceeding.

(d) Awards will be reduced or denied if the applicant has unduly or unreasonably protracted the proceeding or if other special circumstances make an award unjust.

§ 13.6 Allowable fees and expenses.

(a) Awards will be limited to the rates customarily charged by persons engaged in the business of acting as attorneys, agents and expert witnesses. Awards will not be made for more than the applicant's actual expenses. If a party has already received, or is eligible to receive, reimbursement for any expenses under another statutory provision or another program allowing reimbursement, its award under these rules must be reduced by the amount the prevailing party has already received, or is eligible to receive, from the federal government.

(b) An award for the fees of an attorney or agent may not exceed $75.00 per hour, regardless of the actual rate charged by the attorney or agent. An award for the fees of an expert witness may not exceed the highest rate at which the Department pays expert witnesses, which is $24.09 per hour, regardless of the actual rates charged by the witness. These limits apply only to fees; an award may include the reasonable expenses of the attorney, agent, or witness as a separate item, if the attorney, agent or witness ordinarily charges separately for such expenses.

(c) In determining the reasonableness of the fees sought for attorneys, agents or expert witnesses, the adjudicative officer must consider factors bearing on the request, which include, but are not limited to:

(1) If the attorney, agent or witness is in private practice, his or her customary fee for like services; if the attorney, agent or witness is an employee of the applicant, the fully allocated cost of service;

(2) The prevailing rate for similar services in the community in which the attorney, agent or witness ordinarily performs services;

(3) The time actually spent in the representation of the applicant;

(4) The time reasonably spent in light of the difficulty or complexity of the issues in the proceeding; and

(5) Such other factors as may bear on the value of the services provided.

§ 13.7 Studies, exhibits, analyses, engineering reports, tests and projects.

The reasonable cost (or the reasonable portion of the cost) for any study, exhibit, analysis, engineering report, test, project or similar matter prepared on behalf of a party may be awarded to the extent that:

(a) The charge for the service does not exceed the prevailing rate payable for similar services,

(b) The study or other matter was necessary to the preparation for the administrative proceeding, and

(c) The study or other matter was prepared for use in connection with the administrative proceeding. No award will be made for a study or other matter which was necessary to satisfy statutory or regulatory requirements, or which would ordinarily be conducted as part of the party's business irrespective of the administrative proceeding.

Subpart B—Information Required from Applicants

§ 13.10 Contents of application.

(a) Applications for an award of fees and expenses must include:

(1) The name of the applicant and the identification of the proceeding;

(2) A declaration that the applicant believes it has prevailed, and an identification of the position of the Department that the applicant alleges was not substantially justified at the time of the initiation of the proceeding;

(3) Unless the applicant is an individual, a statement of the number of its employees on the date on which the proceeding was initiated, and a brief description of the type and purpose of its organization or business;

(4) A description of any affiliated individuals or entities, as the term "affiliate" is defined in § 13.4(f), or a statement that none exist;

(5) A statement that the applicant's net worth as of the date on which the proceeding was initiated did not exceed $1 million (if an individual) or $5 million (for all other applicants, including their affiliates). However, an applicant may omit this statement if:

(i) It attaches a copy of a ruling by the Internal Revenue Service that it qualifies as an organization described in section 501(c)(3) of the Internal Revenue Code (26 U.S.C. 501(c)(3)) or, in the case of a tax-exempt organization not required to obtain a ruling from the Internal Revenue Service on its exempt status, a statement that describes the basis for the applicant's belief that it qualified under such section; or

(ii) It states that it is a cooperative association as defined in section 15(a) of the Agricultural Marketing Act (12 U.S.C. 1141j(a));

(6) A statement of the amount of fees and expenses for which an award is sought;

(7) A declaration that the applicant has not received, has not applied for, and does not intend to apply for reimbursement of the cost of items listed in the Statement of Fees and Expenses under any other program or statute; or if the applicant has received or applied for or will receive or apply for reimbursement of those expenses under another program or statute, a statement of the amount of reimbursement received or applied for or intended to be applied for; and

(8) Any other matters the applicant wishes the Department to consider in determining whether and in what amount an award should be made.

(b) All applications must be signed by the applicant or by an authorized officer or attorney of the applicant. It shall also contain or be accompanied by a written verification under oath or under penalty of perjury that the information provided in the application is true and correct.

(Approved by the Office of Management and Budget under control number 0990-0118)

§ 13.11 Net worth exhibits.

(a) Each applicant except a qualified tax-exempt organization or cooperative association must provide with its application a detailed exhibit showing the net worth of the applicant and any affiliates (as defined in § 13.4(f) of this part) when the proceeding was initiated. If any individual, corporation, or other entity directly or indirectly controls or owns a majority of the voting shares or other interest of the applicant, or if the applicant directly or indirectly owns or controls a majority of the voting shares or other interest of any corporation or other entity, the exhibit must include a showing of the net worth of all such affiliates or of the applicant including the affiliates. The exhibit may be in any form convenient to the applicant that provides full disclosure of the applicant's and its affiliates' assets and liabilities and is sufficient to determine whether the applicant qualifies under the standards in this part. The adjudicative officer may require an applicant to file additional information to determine its eligibility for an award.

(b) The net worth exhibit shall describe any transfers of assets from, or obligations incurred by, the applicant or any affiliate, occurring in the one year period prior to the date on which the proceeding was initiated, that reduced the net worth of the applicant and its affiliates below the applicable net worth ceiling. If there were no such transactions, the applicant shall so state.

(c) Ordinarily, the net worth exhibit will be included in the public record of the proceeding. However, an applicant that objects to public disclosure of information in any portion of the exhibit and believes there are legal grounds for withholding it from disclosure may submit that portion of the exhibit directly to the adjudicative officer in a sealed envelope labeled "Confidential Financial Information," accompanied by a motion to withhold the information from public disclosure. The motion shall describe the information sought to be withheld and explain, in detail, why it falls within one or more of the specific exemptions from mandatory disclosure under the Freedom of Information Act, 5 U.S.C. 552(b)(1)-(9), why public disclosure of the information would adversely affect the applicant, and why disclosure is not required in the public interest. The material in question shall be served on counsel representing the agency against which the applicant seeks an award, but need not be served on any other party to the proceeding. If the adjudicative officer finds that the information should not be withheld from disclosure, it shall be placed in the public record of the proceeding. Otherwise, the officer will omit the material from the public record. In that case, any decision regarding disclosure of the material (whether in response to a request from an agency or person outside the Department or on the Department's own initiative) will be made in accordance with applicable statutes and Department rules and procedures for commercial and financial records which the submitter claims are confidential or privileged. In particular, this regulation is not a basis for a promise or obligation of confidentiality.

(Approved by the Office of Management and Budget under control number 0990-0118)

§ 13.12 Documentation of fees and expenses.

(a) All applicants must be accompanied by full documentation of the fees and expenses, including the cost of any study, exhibit, analysis, report, test or other similar item, for which the applicant seeks reimbursement.

(b) The documentation shall include an affidavit from each attorney, agent, or expert witness representing or appearing in behalf of the party, stating the actual time expended, the rate at which fees and other expenses were computed, a description of the specific services performed, the total amount claimed, and the total amount paid or payable by the applicant or by any other person or entity for the services provided. Where the adversary adjudication includes covered proceedings (as described in § 13.3) as well as excluded proceedings, or two or more matters, each of which could have been heard separately, the fees and expenses shall be shown separately for each proceeding or matter, and the basis for allocating expenses among the proceedings or matters shall be indicated.

(1) The affidavit shall itemize in detail the services performed by the date, number of hours per date and the services performed during those hours. In order to establish the hourly rate, the affidavit shall state the hourly rate which is billed and paid by the majority of clients during the relevant time periods.

(2) If no hourly rate is paid by the majority of clients because, for instance, the attorney or agent represents most clients on a contingency basis, the attorney or agent shall provide affidavits from two attorneys or agents with similar experience, who perform similar work, stating the hourly rate which they bill and are paid by the majority of their clients during a comparable time period.

(c) If the applicant seeks reimbursement of any expenses not covered by the affidavit described in paragraph (b), the documentation must also include an affidavit describing all such expenses and stating the amounts paid or payable by the applicant or by any other person or entity for the services provided.

(d) The adjudicative officer may require the applicant to provide vouchers, receipts, or other substantiation for any expenses claimed.

(Approved by the Office of Management and Budget under control number 0990-0118)

Subpart C—Procedures for Considering Applications

§ 13.21 Filing and service of pleadings.

All pleadings, including applications for an award of fees, answers, comments, and other pleadings related to the applications, shall be filed in the same manner as other pleadings in the proceeding and served on all other parties and participants, except as provided in § 13.11(b) of this part concerning confidential financial information.

§ 13.22 When an application may be filed.

(a) The applicant must file and serve its application no later than 30 calendar days after the Department's final disposition of the proceeding which makes the applicant a prevailing party.

(b) For purposes of this rule, final disposition means the later of (1) the date on which an initial decision or other recommended disposition of the merits of the proceeding by an adjudicative officer or intermediate review board becomes administratively final; (2) issuance of an order disposing of any petitions for reconsideration of the Department's final order in the proceeding; (3) if no petition for reconsideration is filed, the last date on which such a petition could have been filed; or (4) issuance of a final order or any other final resolution of a proceeding, such as a settlement or voluntary dismissal, which is not subject to a petition for reconsideration.

(c) For purposes of this rule, an applicant has prevailed when the agency has made a final disposition favorable to the applicant with respect to any matter which could have been heard as a separate proceeding, regardless of whether it was joined with other matters for hearing.

(d) If review or reconsideration is sought or taken of a decision as to which an applicant believes it has prevailed, proceedings for the award of fees shall be stayed pending final disposition of the underlying controversy.

§ 13.23 Responsive pleadings.

(a) Within 30 calendar days after service of the application, the agency's litigating party shall file an answer either consenting to the award or explaining in detail any objections to the award requested, and identifying the facts relied on in support of its position. The adjudicative officer may for good cause grant an extension of time for filing an answer.

(b) Within 15 calendar days after service of an answer, the applicant may file a reply. If the reply is based on any alleged facts not already in the record of the proceeding, the applicant shall include with the reply either supporting affidavits or a request for further proceedings under § 13.25.

(c) Any party to or participant in a proceeding may file comments on an application within 30 calendar days, or on an answer within 15 calendar days after service of the application or answer.

§ 13.24 Settlements.

The applicant and the agency's litigating party may agree on a proposed settlement of the award at any time prior to final action on the application. If the parties agree on a proposed settlement of an award before an application has been filed, the application shall be filed with the proposed settlement. All settlements must be approved by the adjudicative officer and the head of the agency or office or his or her designee before becoming final.

§ 13.25 Further proceedings.

(a) Ordinarily, a decision on an application will be made on the basis of the hearing record and pleadings related to the application. However, at the request of either the applicant or the agency's litigating party, or on his or her own initiative, the adjudicative officer may order further proceedings, including an informal conference, oral argument, additional written submissions, or an evidentiary hearing. Such further proceedings shall be held only when necessary for full and fair resolution of the issues arising from the application, and shall be conducted as promptly as possible.

(b) A request that the adjudicative officer order additional written submissions or oral testimony shall identify the information sought and shall explain why the information is necessary to decide the issues.

(c) The adjudicative officer may impose sanctions on any party for failure to comply with his or her order to file pleadings, produce documents, or present witnesses for oral examination. These sanctions may include but are not limited to granting the application partly or completely, dismissing the application, and diminishing the award granted.

§ 13.26 Decisions.

The adjudicative officer shall issue an initial decision on the application as promptly as possible after the filing of the last document or conclusion of the hearing. The decision must include written findings and conclusions on the applicant's eligibility and status as a prevailing party, including a finding on the net worth of the applicant. Where the adjudicative officer has determined under § 13.11(b) that the applicant's net worth information is exempted from disclosure under the Freedom of Information Act, the finding on net worth shall be kept confidential. The decision shall also include, if at issue, findings on whether the agency's position was substantially justified, whether the applicant unduly protracted the proceedings, an explanation of any difference between the amount requested and the amount awarded, and whether any special circumstances make the award unjust.

§ 13.27 Agency review.

(a) The head of the agency or office, or his or her designee, shall review any award granted under this part whether or not the parties request such review, and issue a final decision. No award shall be made under this subpart without approval of the head of the agency or office or his or her designee.

(b) If either the applicant or the agency's litigating party seeks review of the adjudicative officer's decision on the fee application, it shall file and serve exceptions within 30 days after issuance of the initial decision. The head of the agency or office or his or her designee shall issue a final decision on the application as soon as possible or remand the application to the adjudicative officer for further proceedings. Any party that does not file and serve exceptions within the stated time limit loses the opportunity to do so.

§ 13.28 Judicial review.

Judicial review of final agency decisions on awards may be obtained as provided in 5 U.S.C. 504(c)(2).

§ 13.29 Payment of award.

The notification to an applicant of a final decision that an award will be made shall contain the name and address of the appropriate Departmental finance office that will pay the award. An applicant seeking payment of an award shall submit to that finance officer a copy of the final decision granting the award, accompanied by a statement that the applicant will not seek review of the decision in the United States courts. The Department will pay the amount awarded to the applicant within 60 days, unless judicial review of the award or of the underlying decision of the adversary adjudication has been sought by the applicant or any other party to the proceedings.

§ 13.30 Designation of adjudicative officer.

Upon the filing of an application pursuant to § 13.11(a), the officer who presided over the taking of evidence in the proceeding which gave rise to the application will, if available, be automatically designated as the adjudicative officer for the handling of the application.

APPENDIX A

Proceedings covered	Statutory authority	Applicable regulations
Office of the Inspector General		
Proceeding to impose civil monetary penalties or assessments for fraudulent claims under Medicare, Medicaid, and Title V.	42 U.S.C. 1320a-7a	
Health Care Financing Administration		
Proceedings to suspend or revoke licenses of clinical laboratories	42 U.S.C. 263a(e), (g)	
Proceedings provided to a fiscal intermediary before assigning or reassigning Medicare providers to a different fiscal intermediary.	42 U.S.C. 1395h	
Proceedings before the Provider Reimbursement Review Board when HCFA acts as fiscal intermediary	42 U.S.C. 1395oo	42 CFR Part 405, Subpart R.
Food and Drug Administration		
Proceedings to withdraw approval of new drug applications	21 U.S.C. 355(d), (e)	21 CFR Part 12, 21 CFR 314.200.
Proceedings to withdraw approval of new animal drug applications and medicated feed applications	21 U.S.C. 360b(d), (e), (m)	21 CFR Part 12, 21 CFR Part 514, Subpart B.
Proceedings to withdraw approval of medical device premarket approval applications	21 U.S.C. 306e(d), (e), (g)	21 CFR Part 12.
Office of Civil Rights		
Proceedings to enforce Title VI of the Civil Rights Act of 1964, which prohibits descrimination on the basis of race, color or national origin by recipients of Federal financial assistance.	42 U.S.C. 200d-1	45 CFR 80.9.
Proceedings to enforce Section 504 of the Rehabilitation Act of 1973, which prohibits discrimination on the basis of handicap by recipients of Federal financial assistance.	29 U.S.C. 794	45 CFR 84.61.
Proceedings to enforce the Age Discrimination Act of 1975, which prohibits discrimination on the basis of age by recipients of Federal financial assistance.	42 U.S.C 6101, 6104(a)	45 CFR 90.47.
Proceedings to enforce Title IX of the Education Amendments of 1972, which prohibits discrimination on the basis of sex in certain education programs by recipients of Federal financial assistance.	20 U.S.C. 1681, 1682	45 CFR 86.71.

PART 15—UNIFORM RELOCATION ASSISTANCE AND REAL PROPERTY ACQUISITION FOR FEDERAL AND FEDERALLY ASSISTED PROGRAMS

AUTHORITY: Sec. 213, Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, Pub. L. 91-646, 84 Stat. 1894 (42 U.S.C. 4633) as amended by the Surface Transportation and Uniform Relocation Assistance Act of 1987, Title IV of Pub. L. 100-17, 101 Stat. 246-256 (42 U.S.C. 4601 note).

§ 15.1 Uniform relocation assistance and real property acquisition.

Regulations and procedures for complying with the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (Pub. L. 91-646, 84 Stat. 1894, 42 U.S.C. 4601 et seq.), as amended by the Surface Transportation and Uniform Relocation Assistance Act of 1987 (Title IV of Pub. L. 100-17, 101 Stat. 246-256, 42 U.S.C. 4601 note) are set forth in 49 CFR Part 24.

[52 FR 48026, Dec. 17, 1987 and 54 FR 8912, Mar. 2, 1989]

PART 16—PROCEDURES OF THE DEPARTMENTAL GRANT APPEALS BOARD

Sec.

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APPENDIX A—WHAT DISPUTES THE BOARD REVIEWS

AUTHORITY: 5 U.S.C. 301 and secs. 1, 5, 6, and 7 of Reorganization Plan No. 1 of 1953, 18 FR 2053, 67 Stat. 631 and authorities cited in the Appendix.

SOURCE: 46 FR 43817, Aug. 31, 1981, unless otherwise noted.

§ 16.1 What this part does.

This part contains requirements and procedures applicable to certain disputes arising under the HHS programs described in Appendix A. This part is designed to provide a fair, impartial, quick and flexible process for appeal from written final decisions. This part supplements the provisions in Part 74 of this title.

§ 16.2 Definitions.

(a) "Board" means the Departmental Grant Appeals Board of the Department of Health and Human Services. Reference below to an action of "the Board" means an action of the Chair, another Board member, or Board staff acting at the direction of a Board member. In certain instances, the provisions restrict action to particular Board personnel, such as the Chair or a Board member assigned to a case.

(b) Other terms shall have the meaning set forth in Part 74 of this title, unless the context below otherwise requires.

§ 16.3 When these procedures become available.

Before the Board will take an appeal, three circumstances must be present:

(a) The dispute must arise under a program which uses the Board for dispute resolution, and must meet any special conditions established for that program. An explanation is contained in Appendix A.

(b) The appellant must have received a final written decision, and must appeal that decision within 30 days after receiving it. Details of how final decisions are developed and issued, and what must be in them, are contained in 45 CFR 74.304.

(c) The appellant must have exhausted any preliminary appeal process required by regulation. For example, see 42 CFR Part 50 (Subpart D) for Public Health Service programs and Part 75 of this title for rate determinations and cost allocation plans. In such cases, the "final written decision" required for the Board's review is the decision resulting from the preliminiary review or appeal process. Appendix A contains further details.

§ 16.4 Summary of procedures below.

The Board's basic process is review of a written record (which both parties are given ample opportunity to develop), consisting of relevant documents and statements submitted by both parties (see § 16.8). In addition, the Board may hold an informal conference (see § 16.10). The informal conference primarily involves questioning of the participants by a presiding Board member. Conferences may be conducted by telephone conference call. The written record review also may be supplemented by a hearing involving an opportunity for examining evidence and witnesses, cross-examination, and oral argument (see § 16.11). A hearing is more expensive and time-consuming than a determination on the written record alone or with an informal conference. Generally, therefore, the Board will schedule a hearing only if the Board determines that there are complex issues or material facts in dispute, or that the Board's review would otherwise be significantly enhanced by a hearing. Where the amount in dispute is $25,000 or less, there are special expedited procedures (see § 16.12 of this part). In all cases, the Board has the flexibility to modify procedures to ensure fairness, to avoid delay, and to accommodate the peculiar needs of a given case. The Board makes maximum feasible use of preliminary informal steps to refine issues and to encourage resolution by the parties. The Board also has the capability to provide mediation services (see § 16.18).

§ 16.5 How the Board operates.

(a) The Board's professional staff consists of a Chair (who is also a Board member) and full- and part-time Board members, all appointed by the Secretary; and a staff of employees and consultants who are attorneys or persons from other relevant disciplines, such as accounting.

(b) The Chair will assign a Board member to have lead responsibility for each case (the "presiding Board member"). The presiding Board member will conduct the conference or hearing, if one is held. Each decision of the Board is issued by the presiding Board member and two other Board members.

(c) The Board staff assists the presiding Board member, and may request information from the parties; conduct telephone conference calls to request information, to clarify issues, or to schedule events; and assist in developing decisions and other documents in a case.

(d) The Chair will assure that no Board or staff member will participate in a case where his or her impartiality could reasonably be questioned.

(e) The Board's powers and responsibilities are set forth in § 16.13.

§ 16.6 Who represents the parties.

The appellant's notice of appeal, or the first subsequent submission to the Board, should specify the name, address and telephone number of the appellant's representative. In its first submission to the Board and the appellant, the respondent (i.e., the federal party to the appeal) should specify the name, address and telephone number of the respondent's representative.

§ 16.7 The first steps in the appeal process: the notice of appeal and the Board's response.

(a) As explained in 45 CFR 74.304, a prospective appellant must submit a notice of appeal to the Board within 30 days after receiving the final decision. The notice of appeal must include a copy of the final decision, a statement of the amount in dispute in the appeal, and a brief statement of why the decision is wrong.

(b) Within ten days after receiving the notice of appeal, the Board will send an acknowledgment, enclose a copy of these procedures, and advise the appellant of the next steps. The Board will also send a copy of the notice of appeal, its attachments, and the Board's acknowledgment to the respondent. If the Board Chair has determined that the appeal does not meet the conditions of § 16.3 or if further information is needed to make this determination, the Board will notify the parties at this point.

§ 16.8 The next step in the appeal process: preparation of an appeal file and written argument.

Except in expedited cases (generally those of $25,000 or less; see § 16.12 for details), the appellant and the respondent each participate in developing an appeal file for the Board to review. Each also submits written argument in support of its position. The responsibilities of each are as follows:

(a) *The appellant's responsibility.* Within 30 days after receiving the acknowledgment of the appeal, the appellant shall submit the following to the Board (with a copy to the respondent):

(1) An appeal file containing the documents supporting the claim, tabbed and organized chronologically and accompanied by an indexed list identifying each document. The appellant should include only those documents which are important to the Board's decision on the issues in the case.

(2) A written statement of the appellant's argument concerning why the respondent's final decision is wrong (appellant's brief).

(b) *The respondent's responsibility.* Within 30 days after receiving the appellant's submission under paragraph (a) of this section, the respondent shall submit the following to the Board (with a copy to the appellant):

(1) A supplement to the appeal file containing any additional documents supporting the respondent's position, organized and indexed as indicated under paragraph (a) of this section. The respondent should avoid submitting duplicates of documents submitted by the appellant.

(2) A written statement (respondent's brief) responding to the appellant's brief.

(c) *The appellant's reply.* Within 15 days after receiving the respondent's submission, the appellant may submit a short reply. The appellant should avoid repeating arguments already made.

(d) *Cooperative efforts.* Whenever possible, the parties should try to develop a joint appeal file, agree to preparation of the file by one of them, agree to facts to eliminate the need for some documents, or agree that one party will submit documents identified by the other.

(e) *Voluminous documentation.* Where submission of all relevant documents would lead to a voluminous appeal file (for example where review of a disputed audit finding of inadequate documentation might involve thousands of receipts), the Board will consult with the parties about how to reduce the size of the file.

§ 16.9 How the Board will promote development of the record.

The Board may, at the time it acknowledges an appeal or at any appropriate later point, request additional documents or information; request briefing on issues in the case; issue orders to show cause why a proposed finding or decision of the Board should not become final; hold preliminary conferences (generally by telephone) to establish schedules and refine issues; and take such other steps as the Board determines appropriate to develop a prompt, sound decision.

§ 16.10 Using a conference.

(a) Once the Board has reviewed the appeal file, the Board may, on its own or in response to a party's request, schedule an informal conference. The conference will be conducted by the presiding Board member. The purposes of the conference are to give the parties an opportunity to make an oral presentation and the Board an opportunity to clarify issues and question both parties about matters which the Board may not yet fully understand from the record.

(b) If the Board has decided to hold a conference, the Board will consult or correspond with the parties to schedule the conference, identify issues, and discuss procedures. The Board will identify the persons who will be allowed to participate, along with the parties' representatives, in the conference. The parties can submit with their briefs under § 16.8 a list of persons who might participate with them, indicating how each person is involved in the matter. If the parties wish, they may also suggest questions or areas of inquiry which the Board may wish to pursue with each participant.

(c) Unless the parties and the Board otherwise agree, the following procedures apply:

(1) Conferences will be recorded at Department expense. On request, a party will be sent one copy of the transcript. The presiding Board member will insure an orderly transcript by controlling the sequence and identification of speakers.

(2) Only in exceptional circumstances will documents be received at a conference. Inquiry will focus on material in the appeal file. If a party finds that further documents should be in the record for the conference, the party should supplement the appeal file, submitting a supplementary index and copies of the documents to the Board and the other party not less than ten days prior to the conference.

(3) Each party's representative may make an oral presentation. Generally, the only oral communications of other participants will consist of statements requested by the Board or responses to the Board's questions. The Board will allow reply comment, and may allow short closing statements. On request, the Board may allow the participants to question each other.

(4) There will be no post-conference submissions, unless the Board determines they would be helpful to resolve the case. The Board may require or allow the parties to submit proposed findings and conclusions.

§ 16.11 Hearing.

(a) *Electing a hearing.* If the appellant believes a hearing is appropriate, the appellant should specifically request one at the earliest possible time (in the notice of appeal or with the appeal file). The Board will approve a request (and may schedule a hearing on its own or in response to a later request) if it finds there are complex issues or material facts in dispute the resolution of which would be significantly aided by a hearing, or if the Board determines that its decisionmaking otherwise would be enhanced by oral presentations and arguments in an adversary, evidentiary hearing. The Board will also provide a hearing if otherwise required by law or regulation.

(b) *Preliminary conference before the hearing.* The Board generally will hold a prehearing conference (which may be conducted by telephone conference call) to consider any of the following: the possibility of settlement; simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; scheduling the hearing; and any other matter that may aid in resolving the appeal. Normally, this conference will be conducted informally and off the record; however, the Board, after consulting with the parties, may reduce results of the conference to writing in a document which will be made part of the record, or may transcribe proceedings and make the transcript part of the record.

(c) *Where hearings are held.* Hearings generally are held in Washington, D.C. In exceptional circumstances, the Board may hold the hearing at an HHS Regional Office or other convenient facility near the appellant.

(d) *Conduct of the hearing.* (1) The presiding Board member will conduct the hearing. Hearings will be as informal as reasonably possible, keeping in mind the need to establish an orderly record. The presiding Board member generally will admit evidence unless it is determined to be clearly irrelevant, immaterial or unduly repetitious, so the parties should avoid frequent objections to questions and documents. Both sides may make opening and closing statements, may present witnesses as agreed upon in the prehearing conference, and may cross-examine. Since the parties have ample opportunity to develop a complete appeal file, a party may introduce an exhibit at the hearing only after explaining to the satisfaction of the presiding Board member why the exhibit was not submitted earlier (for example, because the information was not available).

(2) The Board may request the parties to submit written statements of witnesses to the Board and each other prior to the hearing so that the hearing will primarily be concerned with cross-examination and rebuttal.

(3) False statements of a witness may be the basis for criminal prosecution under sections 287 and 1001 of Title 18 of the United States Code.

(4) The hearing will be recorded at Department expense.

(e) *Procedures after the hearing.* The Board will send one copy of the transcript to each party as soon as it is received by the Board. At the discretion of the Board, the parties may be required or allowed to submit post-hearing briefs or proposed findings and conclusions (the parties will be informed at the hearing). A party should note any major prejudicial transcript errors in an addendum to its post-hearing brief (or if no brief will be submitted, in a letter submitted within a time limit set by the Board).

§ 16.12 The expedited process.

(a) *Applicability.* Where the amount in dispute is $25,000 or less, the Board will use these expedited procedures, unless the Board Chair determines otherwise under paragraph (b) of this section. If the Board and the parties agree, the Board may use these procedures in cases of more than $25,000.

(b) *Exceptions.* If there are unique or unusually complex issues involved, or other exceptional circumstances, the Board may use additional procedures.

(c) *Regular expedited procedures.* (1) Within 30 days after receiving the Board's acknowledgment of the appeal (see § 16.7), each party shall submit to the Board and the other party any relevant background documents (organized as required under § 16.8), with a cover letter (generally not to exceed ten pages) containing any arguments the party wishes to make.

(2) Promptly after receiving the parties' submissions, the presiding Board member will arrange a telephone conference call to receive the parties' oral comments in response to each other's submissions. After notice to the parties, the Board will record the call. The Board member will advise the parties whether any opportunities for further briefing, submissions or oral presentations will be established. Cooperative efforts will be encouraged (see § 16.8(d)).

(3) The Board may require the parties to submit proposed findings and conclusions.

(d) *Special expedited procedures where there has already been review.* Some HHS components (for example, the Public Health Service) use a board or other relatively independent reviewing authority to conduct a formal preliminary review process which results in a written decision based on a record including documents or statements presented after reasonable notice and opportunity to present such material. In such cases, the following rules apply to appeals of $25,000 or less instead of those under paragraph (c) of this section:

(1) Generally, the Board's review will be restricted to whether the decision of the preliminary review authority was clearly erroneous. But if the Board determines that the record is inadequate, or that the procedures under which the record was developed in a given instance were unfair, the Board will not be restricted this way.

(2) Within 30 days after receiving the Board's acknowledgment of appeal (see § 16.7), the parties shall submit the following:

(i) The appellant shall submit to the Board and the respondent a statement why the decision was clearly erroneous. Unless allowed by the Board after consultation with the respondent, the appellant shall not submit further documents.

(ii) The respondent shall submit to the Board the record in the case. If the respondent has reason to believe that all materials in the record already are in the possession of the appellant, the respondent need only send the appellant a list of the materials submitted to the Board.

(iii) The respondent may, if it wishes, submit a statement why the decision was not clearly erroneous.

(3) The Board, in its discretion, may allow or require the parties to present further arguments or information.

§ 16.13 Powers and responsibilities.

In addition to powers specified elsewhere in these procedures, Board members have the power to issue orders (including "show cause" orders); to examine witnesses; to take all steps necessary for the conduct of an orderly hearing; to rule on requests and motions, including motions to dismiss; to grant extensions of time for good reasons; to dismiss for failure to meet deadlines and other requirements; to close or suspend cases which are not ready for review; to order or assist the parties to submit relevant information; to remand a case for further action by the respondent; to waive or modify these procedures in a specific case with notice to the parties; to reconsider a Board decision where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of these procedures.

§ 16.14 How Board review is limited.

The Board shall be bound by all applicable laws and regulations.

§ 16.15 Failure to meet deadlines and other requirements.

(a) Since one of the objectives of administrative dispute resolution is to provide a decision as fast as possible consistent with fairness, the Board will not allow parties to delay the process unduly. The Board may grant extensions of time, but only if the party gives a good reason for the delay.

(b) If the appellant fails to meet any filing or procedural deadlines, appeal file or brief submission requirements, or other requirements established by the Board, the Board may dismiss the appeal, may issue an order requiring the party to show cause why the appeal should not be dismissed, or may take other action the Board considers appropriate.

(c) If the respondent fails to meet any such requirements, the Board may issue a decision based on the record submitted to that point or take such other measures as the Board considers appropriate.

§ 16.16 Parties to the appeal.

(a) The only parties to the appeal are the appellant and the respondent. If the Board determines that a third person is a real party in interest (for example, where the major impact of an audit disallowance would be on the grantee's contractor, not on the grantee), the Board may allow the third person to present the case on appeal for the appellant or to appear with a party in the case, after consultation with the parties and if the appellant does not object.

(b) The Board may also allow other participation, in the manner and by the deadlines established by the Board, where the Board decides that the intervenor has a clearly identifiable and substantial interest in the outcome of the dispute, that participation would sharpen issues or otherwise be helpful in resolution of the dispute, and that participation would not result in substantial delay.

§ 16.17 Ex parte communications (communications outside the record).

(a) A party shall not communicate with a Board or staff member about matters involved in an appeal without notice to the other party. If such communication occurs, the Board will disclose it to the other party and make it part of the record after the other party has an opportunity to comment. Board members and staff shall not consider any information outside the record (see § 16.21 for what the record consists of) about matters involved in an appeal.

(b) The above does not apply to the following: Communications among Board members and staff; communications concerning the Board's administrative functions or procedures; requests from the Board to a party for a document (although the material submitted in response also must be given to the other party); and material which the Board includes in the record after notice and an opportunity to comment.

§ 16.18 Mediation.

(a) *In cases pending before the Board.* If the Board decides that mediation would be useful to resolve a dispute, the Board, in consultation with the parties, may suggest use of mediation techniques and will provide or assist in selecting a mediator. The mediator may take any steps agreed upon by the parties to resolve the dispute or clarify issues. The results of mediation are not binding on the parties unless the parties so agree in writing. The Board will internally insulate the mediator from any Board or staff members assigned to handle the appeal.

(b) *In other cases.* In any other grants dispute, the Board may, within the limitations of its resources, offer persons trained in mediation skills to aid in resolving the dispute. Mediation services will only be offered at the request, or with the concurrence, of a responsible federal program official in the program under which the dispute arises. The Board will insulate the mediator if any appeal subsequently arises from the dispute.

§ 16.19 How to calculate deadlines.

In counting days, include Saturdays, Sundays, and holidays; but if a due date would fall on a Saturday, Sunday or Federal holiday, then the due date is the next Federal working day.

§ 16.20 How to submit material to the Board.

(a) All submissions should be addressed as follows: Departmental Grant Appeals Board, Room 2004, Switzer Building, 330 C Street SW., Washington, DC 20201.

(b) All submissions after the notice of appeal should identify the Board's docket number (the Board's acknowledgement under § 16.7 will specify the docket number).

(c) Unless the Board otherwise specifies, parties shall submit to the Board an original and two copies of all materials. Each submission other than the notice of appeal, must include a statement that one copy of the materials has been sent to the other party, identifying when and to whom the copy was sent.

(d) Unless hand delivered, all materials should be sent to the Board and the other party by certified or registered mail, return receipt requested.

(e) The Board considers material to be submitted on the date when it is postmarked or hand delivered to the Board.

§ 16.21 Record and decisions.

(a) Each decision is issued by three Board members (see § 16.5(b)), who base their decision on a record consisting of the appeal file; other submissions of the parties; transcripts or other records of any meetings, conferences or hearings conducted by the Board; written statements resulting from conferences; evidence submitted at hearings; and orders and other documents issued by the Board. In addition, the Board may include other materials (such as evidence submitted in another appeal) after the parties are given notice and an opportunity to comment.

(b) The Board will promptly notify the parties in writing of any disposition of a case and the basis for the disposition.

§ 16.22 The effect of an appeal.

(a) *General.* Until the Board disposes of an appeal, the respondent shall take no action to implement the final decision appealed.

(b) *Exceptions.* The respondent may—

(1) Suspend funding (see § 74.114 of this title);

(2) Defer or disallow other claims questioned for reasons also disputed in the pending appeal;

(3) In programs listed in Appendix A, B.(a)(1), implement a decision to disallow Federal financial participation claimed in expenditures reported on a statement of expenditures, by recovering, withholding or offsetting payments, if the decision is issued before the reported expenditures are included in the calculation of a subsequent grant; or

(4) Take other action to recover, withhold, or offset funds if specifically authorized by statute or regulation.

§ 16.23 How long an appeal takes.

The Board has established general goals for its consideration of cases, as follows (measured from the point when the Board receives the first submission after the notice of appeal):

—For regular review based on a written record under § 16.8, 6 months. When a conference under § 16.10 is held, the goal remains at 6 months, unless a requirement for post-conference briefing in a particular case renders the goal unrealistic.

—For cases involving a hearing under § 16.11, 9 months.

—For the expedited process under § 16.12, 3 months.

These are goals, not rigid requirements. The paramount concern of the Board is to take the time needed to review a record fairly and adequately in order to produce a sound decision. Furthermore, many factors are beyond the Board's direct control, such as unforeseen delays due to the parties' negotiations or requests for extensions, how many cases are filed, and Board resources. On the other hand, the parties may agree to steps which may shorten review by the Board; for example, by waiving the right to submit a brief, by agreeing to shorten submission schedules, or by electing the expedited process.

APPENDIX A—WHAT DISPUTES THE BOARD REVIEWS

A. What this Appendix covers.

This appendix describes programs which use the Board for dispute resolution, the types of disputes covered, and any conditions for Board review of final written decisions resulting from those disputes. Disputes under programs not specified in this appendix may be covered in a program regulation or in a memorandum of understanding between the Board and the head of the appropriate HHS operating component or other agency responsible for administering the program. If in doubt, call the Board. Even though a dispute may be covered here, the Board still may not be able to review it if the limits in paragraph F apply.

B. Mandatory grant programs.

(a) The Board reviews the following types of final written decisions in disputes arising in HHS programs authorizing the award of mandatory grants:

(1) Disallowances under Titles I, IV, VI, X, XIV, XVI(AABD), XIX, and XX of the Social Security Act, including penalty disallowances such as those under sections 403(g) and 1903(g) of the Act and fiscal disallowances based on quality control samples.

(2) Disallowances in mandatory grant programs administered by the Public Health Service, including Title V of the Social Security Act.

(3) Disallowances in the programs under sections 113 and 132 of the Developmental Disabilities Act.

(4) Disallowances under Title III of the Older American Act.

(5) Decisions relating to repayment and withholding under block grant programs as provided in 45 CFR 96.52.

(6) Decisions relating to repayment and withholding under State Legalization Impact Assistance Grants as provided in 45 CFR 402.24 and 402.25.

(b) In some of these disputes, there is an option for review by the head of the granting agency prior to appeal to the Board. Where an appellant has requested review by the agency head first, the "final written decision" required by § 16.3 for purposes of Board review will generally be the agency head's decision affirming the disallowance. If the agency head declines to review the disallowance or if the appellant withdraws its request for review by the agency head, the original disallowance decision is the "final written decision." In the latter cases, the 30-day period for submitting a notice of appeal begins with the date of receipt of the notice declining review or with the date of the withdrawal letter.

C. Direct, discretionary project programs.

(a) The Board reviews the following types of final written decisions in disputes arising in any HHS program authorizing the award of direct, discretionary project grants or cooperative agreements:

(1) A disallowance or other determination denying payment of an amount claimed under an award, or requiring return or setoff of funds already received. This does not apply to determinations of award amount or disposition of unobligated balances, or selection in the award document of an option for disposition of program-related income.

(2) A termination for failure to comply with the terms of an award.

(3) A denial of a noncompeting continuation award under the project period system of funding where the denial is for failure to comply with the terms of a previous award.

(4) A voiding (a decision that an award is invalid because it was not authorized by statute or regulation or because it was fraudulently obtained).

(b) Where an HHS component uses a preliminary appeal process (for example, the Public Health Service), the "final written decision" for purposes of Board review is the decision issued as a result of that process.

D. Cost allocation and rate disputes.

The Board reviews final written decisions in disputes which may affect a number of HHS programs because they involve cost allocation plans or rate determinations. These include decisions related to cost allocation plans negotiated with State or local governments and negotiated rates such as indirect cost rates, fringe benefit rates, computer rates, research patient care rates, and other special rates. The "final written decision" for purposes of Board review of these disputes is the decision issued as a result of the preliminary appeal process at Part 75 of this title.

E. SSI agreement disputes.

The Board reviews disputes in the Supplemental Security Income (SSI) program arising under agreements for Federal administration of State supplementary payments under section 1616 of the Social Security Act or mandatory minimum supplements under section 212 of Pub. L. 93-66. In these cases, the Board provides an opportunity to be heard and offer evidence at the Secretarial level of review as set out in the applicable agreements. Thus, the "final written decision" for purposes of Board review is that determination appealable to the Secretary under the agreement.

F. Where Board review is not available.

The Board will not review a decision if a hearing under 5 U.S.C. 554 is required by statute, if the basis of the decision is a violation of applicable civil rights or nondiscrimination laws or regulations (for example, Title VI of the Civil Rights Act), or if some other hearing process is established pursuant to statute.

G. How the Board determines whether it will review a case.

Under § 16.7, the Board Chair determines whether an appeal meets the requirements of this Appendix. If the Chair finds that there is some question about this, the Board will request the written opinion of the HHS component which issued the decision. Unless the Chair determines that the opinion is clearly erroneous, the Board will be bound by the opinion. If the HHS component does not respond within a time set by the Chair, or cannot determine whether the Board clearly does or does not have jurisdiction, the Board will take the appeal.

[46 FR 43817, Aug. 31, 1981, as amended at 47 FR 29492, July 6, 1982; 53 FR 7864, Mar. 10, 1988]

PART 17—RELEASE OF ADVERSE INFORMATION TO NEWS MEDIA

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17.1 Definition.
17.2 Basic poilicy.
17.3 Precautions to be taken.
17.4 Regulatory investigations and trial-type proceedings.
17.5 Context to be reflected.
17.6 Advance notice.
17.7 Retractions or corrections.

AUTHORITY: 5 U.S.C. 301.

SOURCE: 41 FR 3, Jan. 2, 1976, unless otherwise noted.

§ 17.1 Definition.

Adverse information released by an agency means any statement or release by the Department or any principal operating component made to the news media inviting public attention to an action or a finding by the Department or principal operating component of the Department which may adversely affect persons or organizations identified therein. This part does not apply to nor is it affected by any disclosure of records to the public in response to requests made under the Freedom of Information Act (Pub. L. 90-23). The criteria for such disclosures are set forth in the Department's Public Information Regulation (45 CFR Part 5).

§ 17.2 Basic policy.

All adverse information release to news media shall be factual in content and accurate in description. Disparaging terminology not essential to the content and purpose of the publicity shall be avoided.

§ 17.3 Precautions to be taken.

The issuing organization shall take reasonable precautions to assure that information released is accurate and that its release fulfills an authorized purpose.

§ 17.4 Regulatory investigations and trial-type proceedings.

Adverse information relating to regulatory investigations of specifically identified persons or organizations or to pending agency trial-type proceedings shall be released only in limited circumstances in accordance with the criteria outlined below:

(a) Where the Department or a principal operating component determines that there is a significant risk that the public health or safety may be impaired or substantial economic harm may occur unless the public is notified immediately, it may release information to news media as one of the means of notifying the affected public speedily and accurately. However, where the Department or principal operating component determines that public harm can be avoided by immediate discontinuance of an offending practice, a respondent shall be allowed an opportunity, where feasible, to cease the practice (pending a legal test) in lieu of release of adverse information by the agency.

(b) Where it is required in order to bring notice of pending agency adjudication to persons likely to desire to participate therein or likely to be affected by that or a related adjudication, the Department or principal operating component shall rely on the news media to the extent necessary to provide such notice even though it may be adverse to a respondent.

§ 17.5 Context to be reflected.

The authority for and the character of the information shall be made clear, where appropriate, the release shall explain the nature of any studies performed, the sources of relevant data, the areas in which administrative findings of fact were made, and whether the information is based on allegations subject to subsequent adjudication.

§ 17.6 Advance notice.

Any respondent or prospective respondent in an agency proceeding shall, if practicable and consistent with the nature of the proceeding, be given advance notice of information to be released about the proceeding and a reasonable opportunity to prepare in advance a response to the information released.

§ 17.7 Retractions or corrections.

Where the Assistant Secretary for Public Affairs finds that information released by the Department was misleading or a misstatement of fact and any person named therein requests a retraction or correction, the Department shall issue a retraction or correction in the same manner to all of the media outlets that received the original information (or as many of them as is feasible). Where information shown to be misleading or misstatement of fact has been released by a principal operating component of the Department and any person named therein requests a retraction or correction, the agency head shall issue a retraction or correction in the same manner to all of the media outlets that received the original information (or as many of them as is feasible).

PART 30—CLAIMS COLLECTION

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AUTHORITY: Subchapter II of Chapter 37 of Title 31, United States Code, 5 U.S.C. 5514 and 5 U.S.C. 552a as amended by Pub. L. 97-365, 96 Stat. 1749.

SOURCE: 52 FR 264, Jan. 5, 1987, unless otherwise noted.

Subpart A—General

§ 30.1 Purpose and scope.

(a) This regulation prescribes standards and procedures for the officers and employees of the Department, including officers and employees of the various Operating Divisions and regional offices of the Department, charged with collection and disposition of debts owed to the United States.

(b) These standards and procedures will be applied where a statute, regulation or contract does not prescribe different standards or procedures. The authority for the regulation lies in the Federal Claims Collection Act of 1966, as amended, 31 U.S.C. 3711 and 3716-3718; the Federal Claims Collection Standards, at 4 CFR Parts 101-105; related statutes (5 U.S.C. 5512 and 5514, 5 U.S.C. 552a) and regulations (5 CFR Part 550); and the common law. The covered activities include collecting claims in any amount; compromising claims, or suspending or terminating collection of claims that do not exceed $20,000, exclusive of interest and charges; and referring debts that cannot be disposed of by the Department to the Department of Justice or to the General Accounting Office for further administrative action or litigation. Further guidance may be found in the Departmental General Administration Manual, Personnel Manual, Accounting Manual and Grants Administration Manual, and any other manuals which may be issued by each Operating Division, office, or program.

§ 30.2 Definitions.

In this part, unless the context otherwise requires—

—"amounts payable under the Social Security Act" means payments by the Department to beneficiaries, providers, intermediaries, physicians, suppliers, carriers, States, or other contractors or grantees under a Social Security Act program, including: Title I (Grants to States for Old-Age Assistance and Medical Assistance for the Aged); Title II (Federal Old-Age Survivors, and Disability Insurance Benefits); Title III (Grants to States for Unemployment Compensation Administration); Title IV (Grants to States for Aid and Services to Needy Families with Children and for Child-Welfare Services); Title V (Maternal and Child Health and Crippled Children's Services); Title IX (Unemployment Compensation Program); Title X (Grants to States for Aid to the Blind); Title XI, Part B (Peer Review of the Utilization and Quality of Health Care Services); Title XII (Advances to State Unemployment Funds); Title XIV (Grants to States for Aid to Permanently and Totally Disabled); Title XVI (Supplemental Security Income for the Aged, Blind, and Disabled); Title XVII (Grants to States to Fight Mental Retardation); Title XVIII (Medicare); Title XIX (Medicaid); and Title XX (Block Grants to States for Social Services). Federal employee salaries and other payments made by the Department in the course of administering the provisions of the Social Security Act are not deemed to be "payable under" the Social Security Act for purposes of this regulation.

—"claim" or "debt" means an amount of money or other property owed to the United States. Debts include, but are not limited to amounts owed on account of loans made, insured or guaranteed by the United States; salary overpayments to employees; overpayments to program beneficiaries; overpayments to contractors and grantees, including overpayments arising from audit disallowances; excessive cash advances to employees, grantees and contractors; civil penalties and assessments; theft or

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loss of money or property; and damages.

—"debtor" means an individual, organization, association, partnership, corporation, or a State or local government or subdivision indebted to the Department; or the person or entity with legal responsibility for assuming the debtor's obligation.

—"debts arising under the Social Security Act" are overpayments to, or contributions, penalties or assessments owed by, beneficiaries, providers, intermediaries, physicians, suppliers, carriers, States or other contractors or grantees under Titles I, II, III, IV, V, IX, X, XI (Part B), XII, XIV, XVI, XVII, XVIII, XIX and XX of the Social Security Act. Salary overpayments and other debts that result from the administration of the provisions of the Social Security Act are not deemed to "arise under" the Social Security Act for purposes of this regulation.

—"Department" means the United States Department of Health and Human Services and each of its Operating Divisions and regional offices.

—"liquidated or certain in amount" refers to a debt of an amount already fixed and determined by the Secretary, or which may be readily fixed and determined from the information available in the debt file, irrespective of any dispute by the debtor.

—"local government" means a political subdivision, instrumentality, or authority of any State; the District of Columbia; the Commonwealth of Puerto Rico; a territory or possession of the United States; or an Indian tribe, band or nation.

— "Operating Division" means each separate component within the Department of Health and Human Services, and includes the Office of the Secretary, the Office of Human Development Services, the Family Support Administration, the Health Care Financing Administration, the Public Health Service and the Social Security Administration.

— "overdue" refers to a debt not paid by the payment due date specified in the notice of the debt to the debtor (see § 30.13(a)) and not the subject of a repayment agreement approved by the Secretary. Also, a debt subject to repayment agreement is considered overdue if the debtor fails to satisfy his or her obligations under that agreement. "Overdue" and "delinquent" have the same meaning. See 4 CFR 101.2(b).

— "Secretary" means the Secretary of Health and Human Services or the Secretary's designee within any Operating Division or Regional Office.

§ 30.3 Interagency claims.

This regulation does not apply to debts owed by other Federal agencies. These debts will be resolved by negotiation or referral to the General Accounting Office.

§ 30.4 Other administrative proceedings.

This regulation does not supersede or require omission or duplication of administrative proceedings required under contract, statute, regulation or other agency procedures. Examples: Resolution of audit findings under grants or contracts, Chapter 1-105, Grants Administration Manual (GAM); informal grant appeals, 45 CFR Part 75 (Departmental), 42 CFR 50.401 et seq. (Public Health Service); formal appeals to the Departmental Grant Appeals Board, 45 CFR Part 16; and review under a procurement contract Disputes Clause and the Contract Disputes Act of 1978 (41 U.S.C. 601 et seq.), 48 CFR Part 33.

§ 30.5 Other remedies.

The remedies and sanctions available to the Department under this regulation when collecting debts are not intended to be exclusive. The Secretary may impose other appropriate sanctions upon a debtor for inexcusable, prolonged or repeated failure to pay a debt. For example, the Secretary may stop doing business with a grantee, contractor, borrower or lender; convert the method of payment under a grant from an advance to a reimbursement method; or revoke a grantee's letter-of-credit.

§ 30.6 Property claims.

Any person who converts, or negligently loses or destroys personal property belonging, entrusted or loaned to the Department is liable for the

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return of the property or payment of its fair market value. A person who damages such property is liable for the cost of repairs or its fair market value, whichever is less. Collection of these debts means the recovery of the property, its fair market value, or the cost of repairs. Demand for payment of these claims means a demand for the return of the property or for payment of its fair market value or the cost of repairs.

§ 30.7 Claims involving criminal activity or misconduct.

(a) A debtor whose indebtedness involves criminal activity is subject to punishment by fine or imprisonment as well as to a civil claim by the United States for compensation for the misappropriated funds or property. Examples of such activity are fraud, embezzlement and theft or misuse of Government money or property. See 18 U.S.C. 641, 643. The Secretary will refer cases of suspected criminal activity or misconduct to the Office of Inspector General. That office will investigate such cases, refer them to the Department of Justice for criminal prosecution and/or return them to the Secretary for collection, application of administrative sanctions or other disposition.

(b) Debts involving anti-trust violations, fraud, false claims or misrepresentation—

(1) Shall be referred by the Secretary to the Office of Inspector General for review. The Office of Inspector General shall refer the claim back to the Secretary for collection or other disposition to the extent authorized by the Department of Justice.

(2) Shall not be compromised, terminated, suspended or otherwise disposed of by the Secretary under these regulations. Only the Department of Justice is authorized to compromise, terminate, suspend or otherwise dispose of such debts.

§ 30.8 Claims arising from GAO exceptions.

The Secretary may not compromise but will collect, suspend or terminate collection of debts due on account of illegal, improper or incorrect payments shown in General Accounting Office notices of exception issued to certifying or disbursing officers. Only the General Accounting Office has the authority to compromise such debts.

§ 30.9 Subdivision of claims.

Debts may not be subdivided to avoid the monetary ceilings imposed by 31 U.S.C. 3711(a) (2) and (3) on the Secretary's authority to compromise, suspend or terminate collection of debts. A debtor's liability arising from a particular incident or transaction will be considered a single debt in determining whether the claim exceeds $20,000 for purposes of compromising, suspending or terminating collection efforts.

§ 30.10 Omissions not a defense.

Failure by the Secretary to comply with any provision of this regulation may not serve as a defense to any debtor.

Subpart B—Collection of Claims

§ 30.11 Collection rule.

(a) *Aggressive agency action.* The Secretary will take aggressive action to collect debts and reduce delinquencies. Collection efforts shall, at a minimum, normally include sending to the debtor's last known address a total of three progressively stronger written demands for payment at not more than 30-day intervals unless amounts are available for offset under section 30.15, or a response to the first or second demand indicates that further demand would be futile and the debtor's response does not require rebuttal.

(b) *Immediate action.* When necessary to protect the Government's interest, written demand may be preceded by other appropriate action, such as withholding of amounts payable to the debtor or immediate referral of the debt for litigation or filing of a claim in bankruptcy court or against a decedent's estate.

(c) *Finding debtors.* The Secretary will exhaust every reasonable effort to locate debtors, using such sources as telephone directories, city directories, postmasters, driving license records, automobile title and license records in State and local government agencies, the Internal Revenue Service, credit reporting agencies and skip locator services. Referral of a confess-judgment note to the appropriate United States Attorney's Office for entry of judgment will not be delayed because the debtor cannot be located.

(d) *Joint and several liability.* Collection of the full amount of the debt will be pursued from each debtor jointly and severally liable.

(e) *Debtor disputes.* A debtor who disputes a debt must promptly provide available supporting evidence.

(f) *Debt files.* The Secretary will maintain an administrative file for each debt or debtor, documenting the debt(s), all administrative collection action, including communications to and from the debtor, and disposition of the debt(s). Information from a debt file relating to an individual may be disclosed only for purposes consistent with this regulation, the Privacy Act of 1974 (5 U.S.C. 552a), and any other applicable law.

§ 30.12 Notice to debtor.

(a) *Required notice.* The first written demand for payment must inform the debtor of—

(1) The amount and nature of the debt;

(2) The date payment is due, which will generally be 30 days from the date the notice was mailed; and

(3) The assessment under § 30.13 of interest from the date the notice was mailed, and full administrative costs if payment is not received within the 30 days.

(b) *Other notice.* Where applicable, the Secretary must inform the debtor in writing of—(1) His or her right to dispute the debt or request a waiver of the debt, citing the applicable review or waiver authority, the conditions for review or waiver, and the effect of the review or waiver request on collection of the debt, interest, charges and late payment penalties (see § 30.14);

(2) The office, address and telephone number that the debtor should contact to discuss repayment, reconsideration or waiver of the debt;

(3) The proposed sanctions if the debt is overdue, including assessment of late payment penalties under 30.13 (if the debt is more than 90 days overdue) or referral of the debt to a credit reporting agency under § 30.17, or to a collection agency under § 30.18. (See also § 30.5).

(c) *Exception.* This section does not require duplication of any notice already contained in a written agreement, letter or other document signed by, or provided to the debtor.

§ 30.13 Interest, administrative costs and late payment penalties.

(a) *Interest.* (1) Interest will accrue on all debts from the date notice of the debt and the interest requirement is first mailed to the last known address or hand-delivered to the debtor if the debt is not paid within 30 days from the date of mailing of the notice. Except as provided in paragraph (a)(2) of this section, or unless the Secretary determines a higher rate is necessary to protect the Government's interests, the Secretary shall charge an annual rate of interest as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date that the Department becomes entitled to recovery. This rate may be revised quarterly by the Secretary of the Treasury and shall be published by the HHS Assistant Secretary for Management and Budget quarterly in the FEDERAL REGISTER. Debtors who were not paying interest, or were paying interest at a different rate prior to October 25, 1982, may be charged interest at the above-stated rate in effect on the date that notice of the new interest requirement is mailed after 1982. The Secretary may use the advance billing procedure and include the interest notification prior to the debt being owed. Bills sent before a debt is due will include notification of the interest requirement. In these cases, interest will begin to accrue on the day after the due date.

(2) The interest rate established in paragraph (a) of this section shall be no lower than the current value of funds rate, as set by the Secretary of the Treasury pursuant to 31 U.S.C. 3717, except that in the case of installment payment agreements under § 30.19, such rate shall be no lower than the applicable rate determined

from the U.S. Treasury "Schedule of Certified Interest Rates with Range of Maturities."

(3) The Secretary may, at his or her discretion, extend the 30 day interest-free period an additional 30 days if the Secretary determines that such action is in the best interests of the Government, or otherwise warranted by equity and good conscience.

(4) The rate of interest, as initially assessed, will remain fixed for the duration of the indebtedness; except that if a debtor defaults on a repayment agreement, interest may be set at the Treasury rate in effect on the date a new agreement is executed.

(5) Interest will not be charged on interest, administrative costs or late payment penalties required by this section. However, if the debtor defaults on a previous repayment agreement, unpaid accrued interest, charges and late payment penalties under the defaulted agreement may be added to the principal to be paid under a new repayment agreement.

(b) *Administrative costs of collecting overdue debts.* Delinquent debtors will be assessed the administrative costs incurred by the Department as a result of handling and collecting the overdue debts, based on either actual or average costs incurred. These costs will include direct (personnel, supplies, etc.) and indirect costs of collecting inhouse and contracting with collection agencies and may include the costs of providing hearings or any other form of review requested by debtors. *See* § 30.14. These charges will be assessed monthly, or per payment period, throughout the period that the debt is overdue. Such costs may also be additive to other administrative costs if collection is being made for another Federal agency or unit.

(c) *Late payment penalties.* A penalty charge of 6 percent a year will be assessed on a debt, a payment, or any portion thereof that is more than 90 days overdue. Late payment penalty charges will accrue from the date the debt, or portion thereof, became overdue until the overdue amount is paid. These charges will be assessed monthly, or per payment period. See also § 30.14.

(d) *Social Security Act debts.* (1) Unless specifically authorized by statute, regulations or written agreement, or unless the debts arise from, or involve, fraud or criminal activity, the Secretary will not charge interest on debts arising from payments to beneficiaries under Titles II, XVI and XVIII of Social Security Act. The charging of interest is appropriate on debts arising from section 1862(b) of the Act for Medicare payments for which a beneficiary has been reimbursed by a liable third party, in which case the charging of interest would be appropriate.

(2) The Secretary will charge administrative costs or late payment penalties on debts arising under the Social Security Act where authorized by statute, regulations, or written agreement.

(e) *Other debts not covered by 31 U.S.C. 3717.* The Secretary will charge administrative costs or late payment penalties on debts arising under a contract executed prior to, and in effect on October 25, 1982, or debts owed by State or local governments where authorized by statute, regulation, or written agreement.

(f) *Allocation of payments.* Partial or installment payments will be applied first to outstanding administrative cost charges and late payment penalties, second to accrued interest and third to outstanding principal.

(g) *Inactive claims.* Interest, but not administrative cost charges or late payment penalties, will continue to accrue when collection of a debt is suspended under § 30.33(a).

(h) *Waivers.* The Secretary may waive collecting all or part of interest, administrative costs or late payment penalties, if—

(1) The debt or the charges resulted from the agency's error, action or inaction (other than normal processing delays), and without fault on the part of the debtors; or

(2) Collection in any manner authorized under this regulation would defeat the overall objectives of a Departmental program.

§ 30.14 Interest and charges pending waiver or review.

(a) *Rule.* A debtor may either pay the debt, or be liable for interest on the uncollected debt, while a waiver determination, a bona fide dispute or a formal or informal review of the debt is pending. If a final determination is to the effect that any amount was properly a debt to HHS and the debtor chose to retain the amount in dispute, the Secretary shall collect or offset from any future payments to the debtor, an amount equal to the amount of the debt plus interest (as calculated under § 30.13(a)) on such debt amount starting from the date the debtor was first made aware of the debt and ending when such debt is repaid. The debtor will also be assessed administrative cost charges and late payment penalties on the upaid debt for this period if the reviewing or hearing officer determines in writing that the request for a waiver, a hearing or other form of review was spurious.

(b) *Exception.* Interest, late payment penalties and administrative cost charges will not be assessed pending consideration of waiver or review under a statute which prohibits collection of the debt during this period, unless the reviewing or hearing officer determines in writing that the request for a waiver, a hearing or other form of review was spurious.

§ 30.15 Administrative offset.

(a) *Rule.* The Secretary will collect debts owed to the Department by administrative offset if—

(1) The debt is liquidated or certain in amount;

(2) Offset is not expressly or implicitly prohibited by statute or regulation;

(3) Offset is cost-effective or has significant deterrent value;

(4) Offset does not substantially impair or defeat program objectives; and

(5) Overall, offset is best suited to further and protect the Government's interest.

The Secretary may consider financial impact of the proposed offset on the debtor in determining the method and amount of the offset.

(b) *Definitions.* (1) "Administrative Offset" means satisfying a debt by withholding money payable by the Department to, or held by the Department for a debtor. Amounts available for offset include, for example, benefit payments to a program beneficiary overpaid under the same or a different program, amounts due a defaulting or overpaid contractor or grantee under the same or a different agreement, salaries of Federal employees, Federal income tax refunds and judgments held by the debtor against the United States. (Offset against judgments will be effected through the Comptroller General pursuant to 31 U.S.C. 3728.)

(2) "Hearing" means either a review of the record or an oral hearing. A review of the record means a review of the documentary evidence by a designated hearing officer. An oral hearing means an informal conference before a designated hearing officer.

(3) "Hearing officer" is an individual appointed by the Secretary to review and issue a final decision on an employee's dispute of a debt. In the case of an employee debt subject to 5 U.S.C. 5514, the hearing officer may not be an individual under the supervision of the Secretary; will normally be an independent contractor of the Department or an employee of another Federal agency, *see* 4 CFR 102.1 and 5 CFR 550.1107; and may be an administrative law judge if appointment of an independent contractor or an employee of another Federal agency is not feasible.

(4) "Pay" means basic pay, special pay, incentive pay, retired pay, retainer pay, or, in case of an employee not entitled to basic pay, other authorized pay.

(5) "Disposable pay" means the amount that remains from an employee's Federal pay after withholding of all deductions listed in 5 CFR 581.105(b) and any other deductions required by law (including, but not limited to, Federal, State, and local income taxes; Social Security taxes, including Medicare taxes; and Federal retirement programs).

(c) *Scope.* This section satisfies the standards in 4 CFR 102.3 and 102.4 and 5 CFR Part 550, for offset under the common law, 31 U.S.C. 3716, 5 U.S.C. 5514 and any other statute under which standards and procedures for offset have not otherwise been promulgated, including:

(1) Offset of debts owed or to amounts payable, under a grant or contract; except that paragraphs (j)-(p) of this section do not apply. See § 30.4.

(2) Offset of debts owed by former employees from final salary and lump sum payments; and from the Civil Service Retirement and Disability Fund (which also requires compliance with 5 CFR Part 831, Subpart R);

(3) Offset of salary overpayments and other debts under statutes such as 5 U.S.C. 5514 (or 31 U.S.C. 3716 in the case of commissioned officers), travel advances under 5 U.S.C. 5705, training expenses under 5 U.S.C. 4108, debts of employees removed for cause under 5 U.S.C. 5511 and amounts owed by accountable officers under 5 U.S.C. 5512, from the current pay of Federal employees, including employees of the Social Security Administration and other offices administering a Social Security Act program;

(4) Offset of debts owed by state or local governments;

(5) Offset of debts arising, or from amounts payable, under the Social Security Act, except that unless specifically authorized by statute, regulation, or written agreement, or unless the debts arise from, or involve, fraud or criminal activity, administrative offset will not be applied to recover debts arising from, or to withhold, payments to beneficiaries under Titles II, XVI, and XVIII of the Social Security Act with the exception of debts arising from section 1862(b) of the Act for Medicare payments for which a beneficiary has been reimbursed by a liable third party.

(d) *Exceptions.* (1) So long as the conditions listed in paragraphs (a) (2)-(5) and (e) are met, offset may be effected with the debtor's consent without regard to the other provisions in this section.

(2) This section does not apply to debts reduced to judgment, debts already subject to a written repayment or settlement agreement, or debts with respect to which the specified procedures have already been otherwise afforded. Debts reduced to judgment may be offset from the current pay of a Federal employee under Federal Personnel Manual Supplement 552-1.

(3) This section does not apply to any adjustment to a Federal employee's pay arising out of the employee's request for, or change in, coverage under a Federal benefits program such as health or life insurance, which requires periodic deductions from pay, if the amount to be recovered was accumulated over four pay periods or less. Employees consent to deductions from pay whenever they elect or change coverage. Affected employees will receive a notice informing them of these retroactive adjustments to pay and the office to contact if the employee disputes the amount of the adjustment.

(e) *Advance payments.* Under many programs, the Department advances funds to pay for a recipient's anticipated costs. Before offsetting such an advance payment in order to collect a debt, the Secretary may request an assurance that the recipient will incur additional allowable costs whose Federal share is at least equal to the amount of the offset plus the amount of funds actually advanced. If the Secretary believes that the recipient will not incur sufficient costs, the advance will not be offset. In such case, the Secretary may request cash payment or convert the method of paying the recipient from an advance to a reimbursement basis and collect the debt by offsetting payments for costs already incurred.

(f) *Multiple debts.* Amounts available for offset will be applied to multiple debts in accordance with the best interests of the Department and the Government as determined on a case-by-case basis. Other factors being equal, recovery will be equally apportioned, except that debts owed to the Department will be satisfied before debts owed to other Federal agencies.

(g) *Statutory bar to offset.* (1) Administrative offset will not be initiated more than 10 years after the Government's right to collect the debt first accrued, unless facts material to the Government's right to collect the debt were not known and could not reasonably have been known by the officer responsible for discovering or collecting the debt. For this purpose, a debt accrues when it is administratively determined to exist, when it is affirmed by an administrative appeals board or a court having jurisdiction, or when a debtor defaults on a repayment agreement, whichever is later. Offset is initiated when the notice of the proposed offset is mailed to the debtor under paragraph (i) of this section or under other agency procedures, when money payable to the debtor is first withheld, or when the Department requests offset from money held by another agency, whichever is first.

(2) The 10 year statutory bar does not apply to offset of a debt arising out of the Social Security Act. However, offset against such debts will generally not be initiated more than 10 years after the debt accrued unless the Secretary did not previously have the necessary information or the means by which to collect the debt by administrative offset.

(h) *Offset against assigned claims.* The Assignment of Claims Act of 1940, 31 U.S.C. 3727, 41 U.S.C. 15, strictly limits the conditions under which a contractor or any other person or entity entitled to receive payments from the United States may assign his or her rights to the payments to a third party. The Federal Acquisition Regulations implement at 48 CFR Part 32, Subpart 32.8, the statutory conditions to assignment of a contractor's right to be paid by the United States for performance under a Federal procurement contract. A contractor may assign his or her right to payment by the United States only to a bank, trust company, or other financing institution, as security for a loan to the contrator.

(1) The Secretary normally may not collect a debt owed by a contractor by offset from payments due the contractor if the contractor has properly assigned his or her rights to such payments to a financing institution, the assigned payments are due under a contract with a "no setoff" provision, and—

(i) The contractor's debt to the United States arose independently of the contract; or

(ii) The debt arose under the contract because of renegotiation, fines, penalties (other than penalties for noncompliance with the terms of the contract), taxes or social security contributions, or withholding or nonwithholding of taxes or social security contributions. Notwithstanding the satisfaction of all the conditions of this paragraph, offset may be appropriate under certain circumstances, for example: If the financing institution has made neither a loan nor a firm commitment to make a loan under the assignment; or to the extent that the amount due on the contract exceeds the amount of any loans made or expected to be made under a firm commitment.

(2) The Secretary may not offset a debt from payments due any debtor if the debtor has properly assigned his or her right to such payments and the debt arose after the effective date of the assignment.

(3) The Secretary may not attempt to satisfy the assignor's indebtedness by recovering payments already made to the assignee.

(i) *Amount of offset.* Whenever feasible debts will be offset in one lump sum, except that deductions from an employee's current pay pursuant to 5 U.S.C. 5514 may not exceed 15 percent of the employee's disposable pay for any pay period, unless the employee agrees in writing to a larger deduction. However, if the employee retires, resigns, or is discharged, or if his or her employment or active duty otherwise ends, an amount necessary to satisfy the debt may be offset immediately from payments of any nature due the individual.

(j) *Pre-offset requirements.* Before effecting offset, the Secretary will send the debtor written notice of the following—

(1) The nature and amount of the debt;

(2) The agency intention to collect the debt by offsetting the lump sum or installments (stating the amount, frequency, proposed beginning date and duration of the installments) unless the debtor pays the debt or responds within 30 days from the date the notice was mailed to the debtor;

(3) The interest, administrative cost charges and penalties that will or may be assessed under §§ 30.13 and 30.14 if the debt is not paid, or the debtor has not consented to a lump sum offset, within 30 days from the date the notice was mailed to the debtor;

(4) The debtor's right, if a previous opportunity was not provided, to request within 15 days (unless otherwise provided by statute or regulation) from the date of mailing of the notice—

(i) Copies of agency records pertaining to the debt;

(ii) An alternative repayment schedule; or

(iii) A hearing if the debtor contends no debt is owed, the debt is for a different amount, or the proposed offset does not comply with this section;

(5) The debtor's right, if any, to request waiver of the debt, interest or changes, citing the applicable statutory authority, request procedures and waiver conditions and the effect of the waiver request on collection of the debt, interest and charges by offset;

(6) The office, address and telephone number of whom the debtor should address any inquiries or requests;

(7) The requirement that the hearing officer issue a decision at the earliest practical date; except that under 5 U.S.C. 5514, the decision may be issued no later than 60 days after the request for the hearing was filed unless the employee requested and was granted an extension;

(8) That any knowingly false or frivolous statements, representations or evidence may subject the debtor to criminal or civil penalties under 18 U.S.C. 286, 287, 1001 and 1002 or 31 U.S.C. 3729-3731; or also disciplinary action under 5 CFR Part 752 or any other applicable authority if the debtor is an employee;

(9) Any other rights and remedies available to the debtor under the statutes or regulations governing the program under which the debt is being collected; and

(10) That, unless otherwise provided by statute or contract, amounts collected and later waived or found not owed will be promptly refunded.

(k) *Alternative repayment proposal.* A debtor may propose a different offset schedule or repayment by cash installments pursuant to § 30.19.

(l) *Request for hearing.* A debtor may submit to the address specified in the notice letter a written request for a hearing to dispute the administrative determination of the existence or amount of the debt, or whether the proposed offset schedule complies with this section, before the initiation of collection by offset. The request must be postmarked no later than 15 days (unless otherwise provided by statute or regulation) from the date the notice was mailed to the debtor. The debtor must sign the request and briefly state each agency conclusion being disputed and the reasons for the dispute. Supporting facts, witnesses, and documents must be identified in the request. The request, with supporting documents, must, on its face, sufficiently raise a genuine issue of fact or law. Receipt of the request will be acknowledged. The Secretary may grant an extension or excuse a delay if the debtor shows good cause for late filing of a request for a hearing. A reasonable extension will be granted only if the debtor shows that the delay was caused by circumstances beyond the debtor's control or because the debtor did not receive notice, and was not otherwise aware of the time limit. A debtor who fails to meet the filing deadline or to request an extension waives the right to a hearing and will be immediately subject to offset.

(m) *Denial of request.* The Secretary will summarily deny a request for an oral hearing pursuant to a written finding that the request raises no genuine issue of fact or law, or is otherwise spurious or frivolous. In addition, if the Secretary finds that the request raises issues which may properly constitute grounds for waiver of the debt under 5 U.S.C. 5584 or any other statute, the request will be deemed to be a request for a waiver and will be so handled with notification to the debtor.

(n) *Hearings*—(1) *Type of hearing.* The hearing will normally be a review of the record, unless the hearing officer determines that a decision cannot be made without resolving an issue of credibility or veracity, in which case the hearing officer will provide for an oral hearing.

(2) *Date and place of oral hearing.* The oral hearing will normally be held no later than 30 days from the date of receipt by the agency of the request for a hearing. The hearing officer will

give the debtor and the Secretary at least 10 days prior notice of the hearing date, time, place, procedures and issues. The hearing officer, for good cause, may grant the parties each one request to change the hearing date and reschedule the hearing for the earliest practical date. To the extent feasible the hearing will be held at a location convenient to the debtor, and will be open to the public.

(3) *Oral hearing procedures.* The hearing officer will:

(i) Make a summary record of the hearing;

(ii) Decide the order of hearing the evidence;

(iii) Allow the debtor and the agency to introduce relevant evidence not previously submitted and informally call and cross examine witnesses;

(iv) Question parties and witnesses as appropriate;

(v) Allow the debtor and the agency to be represented by counsel; and

(vi) Limit review of the case to the particulars of the agency determination challenged by the debtor.

(o) *Decision of hearing officer.* The hearing officer will issue a written decision at the earliest practical date; but not later than 60 days after a request for a hearing or extension is filed under 5 U.S.C. 5514. The decision will, at a minimum, state the relevant facts, include the hearing officer's analysis, findings and conclusions based on the issues and, if unfavorable to the debtor, inform the debtor of any available rights or remedies.

(p) *Employee waiver requests.* Requests for waiver of overpayments of pay under 5 U.S.C. 5584 will continue to be handled under 4 CFR Parts 91-93 and Chapter 4-40 of the HHS General Administration Manual, except that a waiver request made simultaneously with, or during the pendency of a request for review under this section may be referred for a decision under the waiver standards to the hearing officer reviewing the debt under this section.

(q) *Deductions.* Unless an alternative repayment arrangement has been accepted, the Secretary may initiate offset 30 days after the date that notice of the proposed action was mailed to the debtor if no review or hearing is pending, or as soon as practical after a hearing officer's decision affirming the debt.

(r) *Protection of the Government's interest.* Notwithstanding the provisions of paragraphs (j) through (q) of this section, the Secretary may take immediate action to delay a lump sum or final payment to the debtor whenever such action is necessary to protect the Government's ability to recover the debt by offset. The amount withheld may not exceed the amount of the debt plus any accrued or anticipated interest, administrative cost charges and penalties. The Secretary shall promptly send the debtor the notice specified in paragraph (j) of this section. The Secretary may not take final action to effect offset of the debt from the withheld amount until the procedures required by paragraphs (j) through (l) of this section have been exhausted. The appropriate amount will be paid to the debtor as soon as practical after the debt, or a portion of the debt, is found not to be owed.

(s) *Interagency offsets.* The Secretary may offset a debt owed to another Federal agency from amounts due or payable by the Department to the debtor; or request another Federal agency to offset a debt owed to the Department. Pursuant to 31 U.S.C. 3720a, Department of the Treasury regulations, 26 CFR Part 301, and HHS' implementing regulations, 45 CFR Part 31, the Secretary may seek to offset an overdue debt from a Federal income tax refund due the debtor where reasonable attempts to obtain payment from the debtor have failed.

(1) In attempting to collect a debt from an employee of another Federal agency by deduction from the debtor's pay, the Secretary will follow the procedures set forth in this section. When those procedures are exhausted, a written request for offset will be submitted to the employing agency. The request will—

(i) Certify that the debt is valid;

(ii) Certify the amount and basis of the debt;

(iii) Certify the date the Government's right to collect the debt first accrued;

(iv) Certify that this section has been approved by OPM;

(v) Either—

(A) Certify that the procedures required by this section have been complied with;

(B) Include the employee's written consent to the offset or acknowledgement of receipt of the required procedures; or

(C) If the debt is reduced to judgment, include a copy of the court judgment; and

(vi) Indicate whether collection is to be made in a lump sum or by installments and the number, amount and beginning date of the installments.

(2)(i) The Secretary may deduct from an employee's pay a debt owed to another Federal agency in accordance with this section. The creditor agency must submit the properly certified claim form described in paragraph (s)(1) of this section. No deductions will be made until a properly completed claim form is received.

(ii) Before initiating deductions, the Secretary must send the employee a letter:

(A) Transmitting a copy of the creditor agency's request;

(B) Notifying the employee of the proposed action;

(C) Instructing the employee to contact the creditor agency regarding payment or any dispute of the debt, the certification or the proposed collection; and

(D) Informing the employee of the date that deduction will begin (which should be at the next officially established pay interval) and that deductions will continue until the debt is paid unless the creditor agency directs otherwise.

(iii) The creditor agency must resolve any disputes concerning the debt or the offset and promptly inform the Department of any circumstances affecting the collection by offset. The Department may not review the merits of the creditor agency's decisions.

(iv) The Secretary may temporarily withhold lump sum or final leave payments to the employee who is in the process of separating or to a former employee for no more than 30 days beyond normal processing time periods pending certification.

(v) If the employee subject to salary offset is in the process of separating, and is entitled to payment from the Civil Service Retirement and Disability Fund, the Secretary will send OPM a copy of the creditor agency's original offset request. If the employee transfers to another Federal agency, the Secretary will certify in writing the total amount collected on the debt and send one copy of the certification to the employee and another to the creditor agency, with notice of the transfer. A copy of the certification, along with the creditor agency's original offset request will be inserted in the employee's official personnel folder.

(vi) When a new Department employee transfers from another Federal agency and the employee's official personnel folder contains a creditor agency's offset request to the former employing agency and the former employing agency's certification of the amount of the debt already collected, the Secretary will resume collection by offset. If either item is missing, the creditor agency must comply with paragraph (s)(1).

(t) *Non-waiver of debtor rights by payment.* Unless a statute or contract provides otherwise, a debtor does not waive any rights under law or contract by paying all or part of a debt by offset or cash payment.

(Approved by the Office of Management and Budget under control number 0990-0148)

§ 30.16 Use of credit reporting agencies.

(a) *Overdue debts.* (1) The Secretary will report overdue debts over $100 owed by individuals and all debts over $100 owed by business concerns and private non-profit organizations to consumer or commercial credit reporting agencies. Except as provided in paragraph (a)(3) of this section, beneficiary debts which arise under the Social Security Act may be reported under this section.

(2) Debts owed by individuals, except debts arising under the Social Security Act, will be reported to consumer reporting agencies as defined in 31 U.S.C. 3701(a)(3) pursuant to 5 U.S.C.

552a(b)(12) and 31 U.S.C. 3711(f). The Secretary must first give the individual, but not the corporate debtor at least 60 days written notice that the debt is overdue and will be reported to a credit reporting agency (including the specific information that will be disclosed); that the debtor may dispute the accuracy and validity of the information being disclosed; and, if a previous opportunity was not provided, that the debtor may request review of the debt or rescheduling of payment. The Secretary may disclose only the individual's name, address and social security number, and the nature, amount, status and history of the debt.

(3) Unless specifically authorized by statute, regulation or written agreement, or unless the debts arise from, or involve, fraud or criminal activity, overdue debts arising from payments to beneficaries under Titles II, XVI and XVIII of the Social Security Act will not be reported to credit reporting agencies. All other overdue debts of individuals which arise under the Social Security Act may be reported to credit reporting agencies subject to the conditions stated in paragraph (a)(2) of this section, except that such disclosure would be as a routine use under 5 U.S.C. 552a(b)(3), rather than a disclosure under 552a(b)(12).

(b) *Credit reports and locator services.* The Secretary may also use credit reporting agencies to obtain credit reports to evaluate the financial status of loan applicants and potential contractors and grantees; to obtain credit reports when collecting or disposing of debts to determine a debtor's ability to repay a debt; and to locate debtors. In the case of an individual, the Secretary may disclose, as a routine use under 5 U.S.C. 552a(b)(3), only the individual's name, address, Social Security number and the purpose for which the information will be used.

(c) Disclosures pertaining to individuals may be made to credit reporting agencies generally from the primary systems of records containing information about the debt or the loan, contract or grant application.

(d) Addresses obtained from the Internal Revenue Service may be disclosed to credit reporting agencies only to obtain credit reports (see § 30.21).

§ 30.17 Contracting for collection services.

(a) *Rule.* Except as provided in paragraph (b) of this section, the Secretary may contract for collection services to recover outstanding debts and may pay the contractor's fee from the amounts collected, from funds specifically available for that purpose, or from a revolving fund. The amount of the fee must be consistent with prevailing commercial practice. The Secretary may contract for collection services only if reasonable in-house collection efforts and remedies were, or are likely to be, unsuccessful or not feasible; and the total amount of anticipated recoveries exceeds the total cost of the contract and incidental expenses. The Secretary must retain the authority to resolve disputes, compromise debts, terminate collection action (or recommend such action to the Department of Justice) and refer debts to the Department of Justice for litigation. Contracts for collection services must conform to the standards set forth in the Federal and Departmental Acquisitions Regulations at 48 CFR, Chapters 1 and 3. The Secretary may disclose to the contractor the information about debtors necessary to accomplish the purpose of the contract. The contractor must provide any data from its files relating to the account to the Secretary upon request or upon return of the account. The contractor will be subject to the Privacy Act of 1974, as amended, as specified in 5 U.S.C. 552a(m), and to applicable Federal and State laws and regulations regarding debt collection practices, including the Fair Debt Collection Practices Act, 15 U.S.C. 1692. The contractor will be strictly accountable for all amounts collected.

(b) *Social Security Act debts.* (1) A contractor's fee for collecting debts arising under the Social Security Act may be paid from any funds available for that purpose, but not from the amounts collected unless those amounts belong to a revolving fund.

(2) Unless specifically authorized by statute, regulation or written agreement, or unless the debts arise from,

or involve, fraud or criminal activity, debts arising from payments to beneficiaries under Titles II, XVI and XVIII of the Social Security Act will not be referred to private collection agencies for collection.

§ 30.18 Liquidation of collateral.

If the Secretary holds a security instrument with a power of sale or has physical possession of collateral, the Secretary will liquidate the security or collateral when it is cost-effective to do so and apply the proceeds to an overdue debt. The Secretary will give the debtor reasonable notice of the sale and an accounting of any surplus proceeds and will comply with other requirements under law or contract.

§ 30.19 Installment payments.

The Secretary may enter into a written agreement with a debtor for payment of a debt in regular installments if payment in one lump sum, either by cash or offset, will cause the debtor extreme financial hardship. The debtor must submit sufficient information to determine his or her ability to pay. A request by a debtor for installment payment will delay initiation of offset under § 30.15 only if the request is in writing, is accompanied by a statement with supporting documents indicating how the proposed offset would cause extreme financial hardship and, unless an extension is granted for good cause, is received by the Secretary no later than 15 days (unless otherwise provided by statute or regulation) from the date that notice of the proposed offset was mailed to the debtor. The Secretary will consider factors such as the amount of the debt, the length of the proposed repayment period, whether the debtor is willing to sign a confess-judgment note or give collateral, past dealings with the debtor and documentation indicating that the offset will cause the debtor extreme financial hardship and that the debtor will be financially capable of adhering to the terms of the agreement. The size and frequency of the payments will reasonably relate to the size of the debt and the debtor's present and future ability to pay. Whenever feasible, the installment agreement will provide for full payment of the debt, including interest and charges, in three years or less, and include a security or confess-judgment provision. The full balance, including accrued interest, charges and penalties, will be immediately due and payable if the debtor defaults on any installment made pursuant to a repayment agreement. Interest under installment agreements will be payable at the applicable rate as provided in § 30.13. When a debtor owes several debts and does not designate how an installment payment should be applied as among the various debts, the payment will be applied in accordance with § 30.15(f).

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§ 30.20 Taxpayer information.

(a) The Secretary shall enter into reimbursable agreements with the Internal Revenue Service in accordance with IRS Revenue Procedure 83-29, 26 CFR 601.702, to obtain the current mailing addresses of debtors and to find out whether applicants under included Federal loan programs have overdue tax accounts.

(b) "Included Federal loan program" means any program under which the Department makes, guarantees or insures loans and which appears in the current list of included Federal loan programs published by the Director of the Office of Management and Budget in the FEDERAL REGISTER. An applicant for a loan under an included Federal loan program administered by the Department must furnish his or her taxpayer identification number, which, for an individual, means the Social Security number.

(c) Tax delinquency information may not be redisclosed or used for any other purpose. Addresses obtained from the Internal Revenue Service may be used by the Department, its officers, employees, agents or contractors and other Federal agencies to collect or dispose of debts, but may be disclosed to consumer reporting agencies only to obtain credit reports, unless otherwise independently verified.

§ 30.21 Army hold-up list.

The Secretary may use the Army hold-up list to report indebted contractors to the Department of the Army for inclusion in the list and to check whether a prospective contractor is indebted to another agency. The reported information will be limited to the contractor's name, address and taxpayer identification number if available, and the amount of the debt. The Secretary will promptly report any partial or full satisfaction or waiver of a reported debt and will screen the hold-up list periodically and request removal of any debt of less than $1,000 that has been on the list for over twelve months.

Subpart C—Compromise of Claims

§ 30.22 Compromise rule.

The Secretary may attempt to dispose of debts, including accrued interest, charges and penalties, by compromise settlement whenever the Department's ability to collect the full amount is uncertain because of the debtor's financial status or the litigation risks or because enforced collection would not be cost-effective. When the outstanding principal amount of the debt before compromise exceeds $20,000 and the debtor has exhausted all Departmental administrative remedies, the debt may be compromised only with the approval of the Department of Justice.

§ 30.23 Exceptions.

The Secretary may not compromise debts—

(a) Which arise out of exceptions made by the General Accounting Office in the accounts of accountable officers (only the General Accounting Office has authority to compromise such debts); or

(b) Where there is an indication of fraud, the presentation of a false claim or misrepresentation by the debtor or any other party having an interest in the claim, or where the claim is based on conduct in violation of antitrust laws. (Only the Department of Justice has authority to compromise or terminate collection of these claims.)

§ 30.24 Inability to collect the full amount.

(a) The Secretary may compromise a debt if the full amount cannot be collected because the debtor—

(1) Is unable to pay the full amount within a reasonable time; or

(2) Refuses to pay the full amount and the Government is unable to enforce full collection within a reasonable time.

(b) *Ability to pay.* In determining a debtor's ability to pay, the Secretary may consider the age and health of the individual debtor; present and future income and assets; and the possibility of an improper transfer or concealment of assets by the debtor.

(c) *Amount of compromise.* The amount of compromise will reasonably relate to the amount recoverable by enforced action, considering such factors as State or Federal exemptions available to the debtor, and the price that collateral will bring at a forced sale.

(d) *Installments.* Compromises will be paid in one lump sum whenever possible. Payment by installments may be accepted on a case-by-case basis bearing in mind the conditions specified in § 30.20.

(e) *Credit information.* If reasonably up-to-date credit information to evaluate a compromise proposal is not available, the Secretary may obtain credit reports from credit reporting agencies or a statement from the debtor executed under penalty of perjury showing the debtor's assets and liabilities, income and expenses.

§ 30.25 Litigative probabilities.

The Secretary may compromise a debt if the Government's ability to prove its case in court for the full amount claimed is doubtful either because of the legal issues involved or a bona fide dispute as to the facts. The amount accepted in compromise in such cases should fairly reflect the probability of prevailing on the issues and the prospects for full or partial recovery of a judgment, paying due regard to the availability of evidence and witnesses, and related pragmatic considerations.

§ 30.26 Cost of collecting claim.

The Secretary may compromise a debt if the cost or deterrence value of collection do not justify the enforced collection of the full amount. The amount accepted in compromise in such cases may reflect an appropriate discount for the administrative and litigative costs of collection, taking into account the time which it will take to effect collection. Costs of collection may be a substantial factor in the settlement of small debts, but not normally in the settlement of large debts.

§ 30.27 Enforcement policy.

Statutory penalties, forfeitures, or debts established as an aid to enforcement and to compel compliance may be compromised if not prohibited by law and consistent with the agency's enforcement policy.

§ 30.28 Joint and several liability.

When two or more debtors are jointly and severally liable, a compromise with one debtor will not release the remaining debtors. The amount of a compromise with one debtor will not be considered a precedent or binding in determining the amount which will be required from other debtors jointly and severally liable on the debt.

§ 30.29 Further review of compromise offers.

A debtor's firm written offer of compromise for a substantial amount may be referred to the General Accounting Office or to the Department of Justice when the acceptability of the offer is in doubt. (See 30.36).

§ 30.30 Restriction.

The Secretary may not accept a percentage of a debtor's profits or stock in a debtor corporation in compromise of a debt.

Subpart D—Termination or Suspension of Collection Action

§ 30.31 Termination rule.

(a) The Secretary may terminate collection activity and write off a debt, including accrued interest, charges and penalties if the outstanding principal does not exceed $20,000 and:

(1) The Government cannot collect or enforce collection of any significant sum from the debtor, having due regard for the judicial remedies available to the Government, the debtor's ability to pay (see § 30.25(b)) and the exemptions available to the debtor under State and Federal law;

(2) The debtor cannot be located, there is no security remaining to be liquidated, the applicable statute of limitations has run, and the prospects of collecting by offset are too remote to justify retention of the claim;

(3) The cost of further collection action is likely to exceed the recoverable amount;

(4) The basis for the claim has proved to be unsupportable; or

(5) The evidence necessary to prove the claim cannot be produced or the necessary witnesses are unavailable.

(b) As required by section 61(a)(2) of the Internal Revenue Code, income arising from the discharge in whole or in part of a debt is to be included in the debtor's gross income for the year in which the debt is discharged. The Secretary will report to the Internal Revenue Service, using Form 1099G, any amount over $600 which becomes uncollectible because the applicable statute of limitations expires or because the Government agrees with the debtor to forgive or compromise a debt. An amount which is in dispute, which is discharged under Title 11 of the Bankruptcy Act or which arises out of an overpayment which was already taxed, will not be reported. See IRS Instructions for Form 1096 and Revenue Procedure 83-48 for further instructions.

§ 30.32 Exceptions.

(a) The Secretary may suspend, rather than terminate collection of a debt that arises out of its activities if the outstanding principal does not exceed $20,000 and the Government cannot collect or enforce collection of any significant sum from the debtor (*e.g.*, the debtor cannot be located or is financially unable to pay), but the prospects of future collection are promising enough to justify periodic review of the debt, and there is no statute of limitations problem. Interest will accrue under § 30.13(a).

(b) Where a significant enforcement policy is involved, the Secretary will, instead of terminating or suspending collection, refer debts to the Department of Justice for litigation.

Subpart E—Referrals to the Department of Justice or GAO

§ 30.33 Litigation.

(a) Debts over $600 that cannot be collected or otherwise disposed of by the Secretary or its agents will be referred to the appropriate United States Attorney (if the amount does not exceed $100,000) or the Civil Division of the Department of Justice (if the amount exceeds $100,000) for litigation. Each referral will include all pertinent information, as required by the Claims Collection Litigation Report, including:

(1) The most current address of the debtor or the name and address of the agent for a corporation upon whom service may be made;

(2) Reasonably current credit data in the form of a credit report or a financial statement showing reasonable prospects of enforcing collection from the debtor, having due regard for the exemptions available to the debtor under State and Federal law and the judicial remedies available to the Government; and

(3) A summary of prior collection efforts. Credit data may be omitted if a surety bond, insurance, or the sale of collateral will satisfy the claim in full; or the debtor is in bankruptcy or receivership, or is a unit of State or local government.

(b) Debts of $600 or less, exclusive of interest and charges, may be referred for litigation if a significant enforcement policy is involved or the debtor is clearly able to pay and the Government can effectively enforce payment.

§ 30.34 Claims over $20,000.

The Secretary may compromise or suspend or terminate collection of debts where the outstanding principal exceeds $20,000 only with the approval of, or referral to, the appropriate United States Attorney (if the debt does not exceed $100,000) or the Department of Justice (if the debt exceeds $100,000).

§ 30.35 GAO exceptions.

The Secretary will refer to the General Accounting Office (GAO) debts arising from GAO audit exceptions.

PART 31—REFERRAL OF DEBT TO IRS FOR TAX REFUND OFFSET

Sec.

31.1 Scope.
31.2 Notice of requirements before offset.
31.3 Review within the Department of a determination that an amount is past due and legally enforceable.
31.4 Determination of the hearing officer.
31.5 Review of departmental records related to the debt.
31.6 Stay of offset.
31.7 Application of offset funds: Single debt.
31.8 Application of offset funds: Multiple debts.
31.9 Application of offset funds: Tax refund insufficient to cover amount of debt.
31.10 Time limitation for notifying the IRS to request offset of tax refunds due.
31.11 Correspondence with the Department.

AUTHORITY: 31 U.S.C. 3711, 3716, 3718; Section 2653 of the Deficit Reduction Act (31 U.S.C. 3720A); 26 CFR 301.6402-6T; and 45 CFR Part 30.

SOURCE: 53 FR 25593, July 8, 1988, unless otherwise noted.

§ 31.1 Scope.

(a) The standards set forth in §§ 31.1 through 31.11 are the Department's procedures for requesting the Internal Revenue Service (IRS) to offset tax refunds due taxpayers who have a past due debt obligation to the Department. These procedures are authorized by the Deficit Reduction Act of 1984 (31 U.S.C. 3720A), as implemented by regulation at 26 CFR 301.6402-6T, and apply to the collection of debts as authorized by common law, by 31 U.S.C. 3716, or under other statutory authority.

(b) The Secretary will use the IRS tax refund offset to collect claims which are liquidated or certain in amount, past due and legally enforceable, and which are eligible for tax refund offset under regulations issued by the Secretary of the Treasury.

(c) Except as provided in paragraph (d) of this section, the Secretary will not report debts to the IRS except for the purpose of using the offset procedures described in §§ 31.1 through 31.11. Debts of less than $25.00, exclusive of interest and other charges, will not be reported.

(d) If not legally enforceable because of the lapse of the statute of limitations but otherwise valid, a debt amounting to over $600 will be reported to the IRS as a discharged debt on Form 1099G. (Form 1099G is an information return which government agencies file with the IRS to report discharged debt, and the discharged amount is considered as income to the taxpayer.) [See § 31.9; 45 CFR 30.31(b).]

§ 31.2 Notice of requirements before offset.

A request for reduction of an IRS tax refund will be made only after the Secretary makes a determination that an amount is owed and past due and provides the debtor with 60 calendar days written notice. The Department's Notice of Intent to Collect by IRS Tax Refund Offset (Notice of Intent) will state:

(a) The nature and amount of the debt;

(b) That unless the debt is repaid within 60 calendar days from the date of the Department's Notice of Intent, the Secretary intends to collect the debt by requesting the IRS to reduce any amounts payable to the debtor as refunds of Federal taxes paid by an amount equal to the amount of the debt and all accumulated interest and other charges;

(c) That the debtor has a right to obtain review, within the Department, of the Secretary's initial determination that the debt is past due and legally enforceable (*See* § 31.3); and

(d) That the debtor has a right to inspect and copy departmental records related to the debt as determined by the Secretary and will be informed as to where and when the inspection and copying can be done after the Department receives notice from the debtor that inspection and copying are requested (*See* § 31.5).

§ 31.3 Review within the Department of a determination that an amount is past due and legally enforceable.

(a) *Notification by debtor.* A debtor who receives a Notice of Intent has the right to present evidence that all or part of the debt is not past due or not legally enforceable. To exercise this right, the debtor shall send a letter notifying the applicable delegatee of the HHS Departmental Claims Officer specified in § 31.11 that the debtor intends to present evidence to a designated hearing officer. The letter must be received by such designated claims officer within 60 calendar days from the date of the Department's Notice of Intent.

(b) *Submission of evidence.* The debtor may submit evidence showing that all or part of the debt is not past due or not legally enforceable along with the notification required by paragraph (a) of this section. Failure to submit the notification and evidence within 60 calendar days will result in an automatic referral of the debt to the IRS without further action. Evidence submitted by a debtor who has requested prior review of a claim under 45 CFR Part 30 will not be reconsidered unless such evidence raises a new defense not considered in connection with such prior review.

(c) *Review of the record.* After a timely submission of evidence by the debtor, the claims officer will submit such evidence to a designated hearing officer, who will review all material related to the debt which is in possession of the Department. The hearing officer shall make a determination based upon a review of the written record, except that the hearing officer may order an oral hearing if the officer finds that:

(1) An applicable statute authorizes or requires the Secretary to consider waiver of the indebtedness and the waiver determination turns on credibility or veracity; or

(2) The question of indebtedness cannot be resolved by review of the documentary evidence.

§ 31.4 Determination of the hearing officer.

(a) Following the hearing or the review of the record, the hearing officer shall issue a written decision which includes the supporting rationale for the decision. The decision of the hearing officer concerning whether a debt or part of a debt is past due and legally enforceable is the final agency decision with respect to the past due status and enforceability of the debt.

(b) Copies of the hearing officer's decision will be distributed to the designated claims officer, the Department's Office of the Assistant Secretary for Management and Budget, the debtor, and the debtor's attorney or other representative, if any.

(c) If the hearing officer's decision affirms that all or part of the debt is past due and legally enforceable, the Secretary will notify the IRS after the hearing officer's determination has been issued under paragraph (a) of this section and a copy of the determination is received by the Department's Office of the Assistant Secretary for Management and Budget. No referral will be made to the IRS if review of the debt by the hearing officer reverses the initial decision that the debt is past due and legally enforceable.

§ 31.5 Review of departmental records related to the debt.

(a) *Notification by debtor.* A debtor who intends to inspect or copy departmental records related to the debt as determined by the Secretary must send a letter to the designated claims officer stating the debtor's intention. The letter must be received by the designated claims officer within 60 calendar days from the date of the Department's Notice of Intent.

(b) *Department's response.* In response to timely notification by the debtor as described in paragraph (a) of this section, the designated claims officer will notify the debtor of the location and time when the debtor may inspect or copy departmental records related to the debt. At his or her discretion, the designated claims officer may also mail copies of the debt-related records to the debtor.

§ 31.6 Stay of offset.

If the debtor timely notifies the Secretary that the debtor is exercising a right described in § 31.3(a) and timely submits evidence pursuant to § 31.3(b), any notice to the IRS will be stayed until the issuance of a written decision by the hearing officer which determines that a debt or part of a debt is past due and legally enforceable.

§ 31.7 Application of offset funds: Single debt.

If the debtor does not timely notify the Secretary that the debtor is exercising a right described in § 31.3, the Secretary will notify the IRS of the debt 60 calendar days from the date of the Department's Notice of Intent, and will request that the amount of the debt be offset against any amount payable by the IRS as refund of Federal taxes paid. Normally, recovered funds will be applied first to any special charges provided for in HHS regulations or contracts, then to interest, and finally, to the principal owed by the debtor.

§ 31.8 Application of offset funds: Multiple debts.

The Secretary will use the procedures set out in § 31.7 for the offset of multiple debts. However, when collecting on multiple debts the Secretary will apply the recovered amounts against the debts in order in which the debts accrued.

§ 31.9 Application of offset funds: Tax refund insufficient to cover amount of debt.

If a tax refund is insufficient to satisfy a debt in a given tax year, the Secretary will recertify to the IRS on the following year to collect further on the debt. If, in the following year, the debt has become legally unenforceable because of the lapse of the statute of limitations, the debt will be reported to the IRS as a discharged debt in accordance with § 31.1(d) and 45 CFR 30.31(b).

§ 31.10 Time limitation for notifying the IRS to request offset of tax refunds due.

(a) The Secretary may not initiate offset of tax refunds due to collect a debt for which authority to collect arises under 31 U.S.C. 3716 more than 10 years after the Secretary's right to collect the debt first accrued, unless facts material to the Secretary's right to collect the debt were not known and could not reasonably have been known by the officials of the Department who were responsible for discovering and collecting such debts.

(b) When the debt first accrued is determined according to existing law regarding the accrual of debts. (*See*, for example, 28 U.S.C. 2415.)

§ 31.11 Correspondence with the Department.

(a) All correspondence from the debtor to the Secretary concerning the right to review as described in § 31.3 shall be addressed to the appropriate office of the Department at the following locations:

Office of the Secretary: Office of Financial Operations, Room 705D, Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201

Public Health Service: PHS Claims Office, Room 18-20, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

Social Security Administration: SSA Claims Office, P.O. Box 17042, Baltimore, Maryland 21235

Health Care Financing Administration: HCFA Claims Office, Division of Accounting, P.O. Box 17255, Baltimore, Maryland 21203

Family Support Administration: FSA Claims Office, Switzer Building, Room 2222, 330 C Street SW., Washington, DC 20201

Region I: Office of the General Counsel, John F. Kennedy Federal Building, Room 2047, Boston, Massachusetts 02203

Region II: Office of the General Counsel, Jacob K. Javits Federal Building, Room 3908, New York, New York 10278

Region III: Office of the General Counsel, 3535 Market Street, Room 9100, P.O. Box 13716, Philadelphia, Pennsylvania 19101

Region IV: Office of the General Counsel, 101 Marietta Tower, Room 221, Atlanta, Georgia, 30323

Region V: Office of the General Counsel, 18th Floor, 300 South Wacker Drive, Chicago, Illinois 60606

Region VI: Office of the General Counsel, 1200 Main Tower, Room 1330, Dallas, Texas 75202

Region VII: Office of the General Counsel, 601 East 12th Street, Room 535, Kansas City, Missouri 64106

Region VIII: Office of the General Counsel, 1961 Stout Street, Room 1106, Denver, Colorado 80294

Region IX: Office of the General Counsel, 50 United Nations Plaza, Room 420, San Francisco, California 94102

Region X: Office of the General Counsel, 2901 3rd Avenue, Room 580, Seattle, Washington, 98121.

(b) All other correspondence shall be addressed to the appropriate office as described in paragraph (a) of this section. All requests for review of departmental records must be marked: *Attention: Records Inspection Request.*

PART 35—TORT CLAIMS AGAINST THE GOVERNMENT

Subpart A—General

Sec.

35.1 Scope of regulations.

Subpart B—Procedures

35.2 Administrative claim; when presented; place of filing.
35.3 Administrative claim; who may file.
35.4 Administrative claims; evidence and information to be submitted.
35.5 Investigation, examination, and determination of claims.
35.6 Final denial of claim.
35.7 Payment of approved claims.
35.8 Release.
35.9 Penalties.
35.10 Limitation on Department's authority.

AUTHORITY: Sec. 1(a), 80 Stat. 306; 28 U.S.C. 2672; 28 CFR Part 14.

SOURCE: 32 FR 14101, Oct. 11, 1967, unless otherwise noted.

Subpart A—General

§ 35.1 Scope of regulations.

The regulations in this part shall apply only to claims asserted under the Federal Tort Claims Act, as amended, 28 U.S.C. sections 2671-2680, accruing on or after January 18, 1967, for money damages against the United States for damage to or loss of property or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Department of Health and Human Services while acting within the scope of his office or employment.

Subpart B—Procedures

§ 35.2 Administrative claim; when presented; place of filing.

(a) For purposes of the regulations in this part, a claim shall be deemed to have been presented when the Department of Health and Human Services receives, at a place designated in paragraph (b) of this section, an executed Standard Form 95 or other written notification of an incident accompanied by a claim for money damages in a sum certain for damage to or loss of property, for personal injury, or for death, alleged to have occurred by reason of the incident. A claim which should have been presented to the Department but which was mistakenly addressed to or filed with another Federal agency, shall be deemed to be presented to the Department as of the date that the claim is received by the Department. A claim mistakenly addressed to or filed with the Department shall forthwith be transferred to the appropriate Federal agency, if ascertainable, or returned to the claimant.

(b) A claim presented in compliance with paragraph (a) of this section may be amended by the claimant at any time prior to final action by the Department Claims Officer or prior to the exercise of the claimant's option to bring suit under 28 U.S.C. 2675(a). Amendments shall be submitted in writing and signed by the claimant or his duly authorized agent or legal representative. Upon the timely filing of an amendment to a pending claim, the Department shall have 6 months in which to make a final disposition of the claim as amended and the claimant's option under 28 U.S.C. 2675(a) shall not accrue until 6 months after the filing of an amendment.

(c) Forms may be obtained and claims may be filed, with the office, local, regional, or headquarters, of the constituent organization having jurisdiction over the employee involved in the accident or incident, or with the Department of Health and Human Services Claims Officer, Washington, D.C. 20201.

[32 FR 14101, Oct. 11, 1967, as amended at 35 FR 4517, Mar. 13, 1970]

§ 35.3 Administrative claim; who may file.

(a) A claim for injury to or loss of property may be presented by the owner of the property interest which is the subject of the claim, his duly authorized agent, or his legal representative.

(b) A claim for personal injury may be presented by the injured person, his duly authorized agent, or his legal representative.

(c) A claim based on death may be presented by the executor or administrator of the decedent's estate or by any other person legally entitled to assert such a claim under applicable state law.

(d) A claim for loss wholly compensated by an insurer with the rights of a subrogee may be presented by the insurer. A claim for loss partially compensated by an insurer with the rights of a subrogee may be presented by the insurer or the insured individually, as their respective interests appear, or jointly. Whenever an insurer presents a claim asserting the rights of a subrogee, he shall present with his claim appropriate evidence that he has the rights of a subrogee.

(e) A claim presented by an agent or legal representative shall be presented in the name of the claimant, be signed by the agent or legal representative, show the title or legal capacity of the person signing, and be accompanied by evidence of his authority to present a claim on behalf of the claimant as agent, executor, administrator, parent, guardian, or other representative.

§ 35.4 Administrative claims; evidence and information to be submitted.

(a) *Death.* In support of a claim based on death, the claimant may be required to submit the following evidence or information:

(1) An authenticated death certificate or other competent evidence showing cause of death, date of death, and age of the decedent.

(2) Decedent's employment or occupation at time of death, including his monthly or yearly salary or earnings (if any), and the duration of his last employment or occupation.

(3) Full names, addresses, birth dates, kinship, and marital status of the decedent's survivors, including identification of those survivors who were dependent for support upon the decedent at the time of his death.

(4) Degree of support afforded by the decedent to each survivor dependent upon him for support at the time of his death.

(5) Decedent's general physical and mental condition before death.

(6) Itemized bills for medical and burial expenses incurred by reason of the incident causing death, or itemized receipts of payments for such expenses.

(7) If damages for pain and suffering prior to death are claimed, a physician's detailed statement specifying the injuries suffered, duration of pain and suffering, any drugs administered for pain and the decedent's physical condition in the interval between injury and death.

(8) Any other evidence or information which may have a bearing on either the responsibility of the United States for the death or the damages claimed.

(b) *Personal injury.* In support of a claim for personal injury, including pain and suffering, the claimant may be required to submit the following evidence or information:

(1) A written report by his attending physician or dentist setting forth the nature and extent of the injury, nature and extent of treatment, any degree of temporary or permanent disability, the prognosis, period of hospitalization, and any diminished earning capacity. In addition, the claimant may be required to submit to a physical or mental examination by a physician employed or designated by the Department or the constituent organization. A copy of the report of the examining physician shall be made available to the claimant upon the claimant's written request provided that claimant has, upon request, furnished the report referred to in the first sentence of this subparagraph and has made or agrees to make available to the Department or the operating agency any other physician's reports previously or thereafter made of the physical or mental condition which is the subject matter of his claim.

(2) Itemized bills for medical, dental, and hospital expenses incurred, or itemized receipts of payment for such expenses.

(3) If the prognosis reveals the necessity for future treatment, a statement of expected duration of and expenses for such treatment.

(4) If a claim is made for loss of time from employment, a written statement from his employer showing actual time lost from employment, whether he is a full or part-time employee, and wages or salary actually lost.

(5) If a claim is made for loss of income and the claimant is self-employed, documentary evidence showing the amount of earnings actually lost.

(6) Any other evidence or information which may have a bearing on either the responsibility of the United States for the personal injury or the damages claimed.

(c) *Property damage.* In support of a claim for damage to or loss of property, real or personal, the claimant may be required to submit the following evidence or information:

(1) Proof of ownership.

(2) A detailed statement of the amount claimed with respect to each item of property.

(3) An itemized receipt of payment for necessary repairs or itemized written estimates of the cost of such repairs.

(4) A statement listing date of purchase, purchase price, market value of the property as of date of damage, and salvage value, where repair is not economical.

(5) Any other evidence or information which may have a bearing either on the responsibility of the United States for the injury to or loss of property or the damages claimed.

(d) *Time limit.* All evidence required to be submitted by this section shall be furnished by the claimant within a reasonable time. Failure of a claimant to furnish evidence necessary to a determination of his claim within three months after a request therefor has been mailed to his last known address may be deemed an abandonment of the claim. The claim may be thereupon disallowed.

§ 35.5 Investigation, examination, and determination of claims.

When a claim is received, the constituent agency out of whose activities the claim arose shall make such investigation as may be necessary or appropriate for a determination of the validity of the claim and thereafter shall forward the claim, together with all pertinent material, and a recommendation based on the merits of the case, with regard to allowance or disallowance of the claim, to the Department Claims Officer to whom authority has been delegated to adjust, determine, compromise and settle all claims hereunder.

§ 35.6 Final denial of claim.

(a) Final denial of an administrative claim shall be in writing and sent to the claimant, his attorney, or legal representative by certified or registered mail. The notification of final denial may include a statement of the reasons for the denial and shall include a statement that, if the claimant is dissatisfied with the Department's action, he may file suit in an appropriate U.S. District Court not later than 6 months after the date of mailing of the notification.

(b) Prior to the commencement of suit and prior to the expiration of the 6-month period after the date of mailing, by certified or registered mail of notice of final denial of the claim as provided in 28 U.S.C. 2401(b), a claimant, his duly authorized agent, or legal representative, may file a written request with the Department for reconsideration of a final denial of a claim under paragraph (a) of this section. Upon the timely filing of a request for reconsideration the Department shall have 6 months from the date of filing in which to make a final disposition of the claim and the claimant's option under 28 U.S.C. 2675(a) to bring suit shall not accrue until 6 months after the filing of a request for reconsideration. Final Department action on a request for reconsideration shall be effected in accordance with the provisions of paragraph (a) of this section.

[32 FR 14101, Oct. 11, 1967, as amended at 35 FR 4517, Mar. 13, 1970]

§ 35.7 Payment of approved claims.

(a) Upon allowance of his claim, claimant or his duly authorized agent shall sign the voucher for payment, Standard Form 1145, before payment is made.

(b) When the claimant is represented by an attorney, the voucher for payment (SF 1145) shall designate both the claimant and his attorney as "payees." The check shall be delivered to the attorney whose address shall appear on the voucher.

§ 35.8 Release.

Acceptance by the claimant, his agent or legal representative, of any award, compromise or settlement made hereunder, shall be final and conclusive on the claimant, his agent or legal representative and any other person on whose behalf or for whose benefit the claim has been presented, and shall constitute a complete release of any claim against the United States and against any employee of the Government whose act or omission gave rise to the claim, by reason of the same subject matter.

§ 35.9 Penalties.

A person who files a false claim or makes a false or fraudulent statement in a claim against the United States may be liable to a fine of not more than $10,000 or to imprisonment of not more than 5 years, or both (18 U.S.C. 287.1001), and, in addition, to a forfeiture of $2,000 and a penalty of double the loss or damage sustained by the United States (31 U.S.C. 231).

§ 35.10 Limitation on Department's authority.

(a) An award, compromise or settlement of a claim hereunder in excess of $25,000 shall be effected only with the prior written approval of the Attorney General or his designee. For the purposes of this paragraph, a principal claim and any derivative or subrogated claim shall be treated as a single claim.

(b) An administrative claim may be adjusted, determined, compromised or settled hereunder only after consultation with the Department of Justice when, in the opinion of the Department:

(1) A new precedent or a new point of law is involved; or

(2) A question of policy is or may be involved; or

(3) The United States is or may be entitled to indemnity or contribution from a third party and the Department is unable to adjust the third party claim; or

(4) The compromise of a particular claim, as a practical matter, will or may control the disposition of a related claim in which the amount to be paid may exceed $25,000.

(c) An administrative claim may be adjusted, determined, compromised or settled only after consultation with the Department of Justice when it is learned that the United States or an employee, agent or cost plus contractor of the United States is involved in litigation based on a claim arising out of the same incident or transaction.

PART 36—INDEMNIFICATION OF HHS EMPLOYEES

§ 36.1 Policy.

(a) The Department of Health and Human Services may indemnify, in whole or in part, its employees (which for the purpose of this regulation includes former employees) for any verdict, judgment or other monetary award which is rendered against any such employee, provided that the conduct giving rise to the verdict, judgment or award was taken within the scope of his or her employment with the Department and that such indemnification is in the interest of the United States, as determined by the Secretary, or his or her designee, in his or her discretion.

(b) The Department of Health and Human Services may settle or compromise a personal damage claim against its employee by the payment of available funds, at any time, provided the alleged conduct giving rise to the personal damage claim was taken within the scope of employment and that such settlement or compromise is in the interest of the United States, as determined by the Secretary, or his or her designee, in his or her discretion.

(c) Absent exceptional circumstances, as determined by the Secretary or his or her designee, the Department will not entertain a request either to agree to indemnify or to settle a personal damage claim before entry of an adverse verdict, judgment or monetary award.

(d) When an employee of the Department of Health and Human Services becomes aware that an action has been filed against the employee in his or her individual capacity as a result of conduct taken within the scope of his or her employment, the employee should immediately notify the Department that such an action is pending.

(e) The employee may, thereafter, request either (1) indemnification to satisfy a verdict, judgment or award entered against the employee or (2) payment to satisfy the requirements of a settlement proposal. The employee shall submit a written request, with documentation including copies of the verdict, judgment, award or settlement proposal, as appropriate, to the head of his employing component, who shall thereupon submit to the General Counsel, in a timely manner, a recommended disposition of the request. The General Counsel shall also seek the views of the Department of Justice. The General Counsel shall forward the request, the employing component's recommendation and the General Counsel's recommendation to the Secretary for decision.

(f) Any payment under this section either to indemnify a Department of Health and Human Services employee or to settle a personal damage claim shall be contingent upon the availability of appropriated funds of the employing component of the Department of Health and Human Services.

AUTHORITY: 5 U.S.C. 301.

[53 FR 11280, Apr. 6, 1988]

PART 46—PROTECTION OF HUMAN SUBJECTS

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AUTHORITY: 5 U.S.C. 301; sec. 474(a), 88 Stat. 352 (42 U.S.C. 289*l*-3(a)).

EDITORIAL NOTE: The Department of Health and Human Services issued a notice of waiver regarding the requirements set forth in Part 46, relating to protection of human subjects, as they pertain to demonstration projects, approved under section 1115 of the Social Security Act, which test the use of cost—sharing, such as deductibles, copayment and coinsurance, in the Medicaid program. For further information see 47 FR 9208, Mar. 4, 1982.

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

SOURCE: 46 FR 8386, Jan. 26, 1981, unless otherwise noted.

§ 46.101 To what do these regulations apply?

(a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving human subjects conducted by the Department of Health and Human Services or funded in whole or in part by a Department grant, contract, cooperative agreement or fellowship.

(1) This includes research conducted by Department employees, except each Principal Operating Component head may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or funded by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of this section waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from these regulations unless the research is covered by other subparts of this part:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(3) Research involving survey or interview procedures, except where all of the following conditions exist: (i) Responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

(4) Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist:

(i) Observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects,

(ii) The observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and

(iii) The research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

(5) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(6) Unless specifically required by statute (and except to the extent specified in paragraph (i)), research and demonstration projects which are conducted by or subject to the approval of the Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine:

(i) Programs under the Social Security Act, or other public benefit or service programs;

(ii) Procedures for obtaining benefits or services under those programs;

(iii) Possible changes in or alternatives to those programs or procedures; or

(iv) Possible changes in methods or levels of payment for benefits or services under those programs.

(c) The Secretary has final authority to determine whether a particular activity is covered by these regulations.

(d) The Secretary may require that specific research activities or classes of research activities conducted or funded by the Department, but not otherwise covered by these regulations, comply with some or all of these regulations.

(e) The Secretary may also waive applicability of these regulations to specific research activities or classes of research activities, otherwise covered by these regulations. Notices of these actions will be published in the FEDERAL REGISTER as they occur.

(f) No individual may receive Department funding for research covered by these regulations unless the individual is affiliated with or sponsored by an institution which assumes responsibility for the research under an assurance satisfying the requirements of this part, or the individual makes other arrangements with the Department.

(g) Compliance with these regulations will in no way render inapplicable pertinent federal, state, or local laws or regulations.

(h) Each subpart of these regulations contains a separate section describing to what the subpart applies. Research which is covered by more than one subpart shall comply with all applicable subparts.

(i) If, following review of proposed research activities that are exempt from these regulations under paragraph (b)(6), the Secretary determines that a research or demonstration project presents a danger to the physical, mental, or emotional well-being of a participant or subject of the research or demonstration project, then federal funds may not be expended for such a project without the written, informed consent of each participant or subject.

[46 FR 8386, Jan. 26, 1981; 46 FR 19195, Mar. 27, 1981, as amended at 48 FR 9269, Mar. 4, 1983]

§ 46.102 Definitions.

(a) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) "Department" or "HHS" means the Department of Health and Human Services.

(c) "Institution" means any public or private entity or agency (including federal, state, and other agencies).

(d) "Legally authorized representative" means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(e) "Research" means a systematic investigation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute "research" for purposes of these regulations, whether or not they are supported or funded under a program which is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities.

(f) "Human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(h) "Certification" means the official notification by the institution to the Department in accordance with the requirements of this part that a research project or activity involving human subjects has been reviewed and approved by the Institutional Review Board (IRB) in accordance with the approved assurance on file at HHS. (Certification is required when the research is funded by the Department and not otherwise exempt in accordance with § 46.101(b)).

[46 FR 8386, Jan 26, 1981; 46 FR 19195, Mar. 27, 1981]

§ 46.103 Assurances.

(a) Each institution engaged in research covered by these regulations shall provide written assurance satisfactory to the Secretary that it will comply with the requirements set forth in these regulations.

(b) The Department will conduct or fund research covered by these regulations only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the Secretary that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. This assurance shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of source of funding. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of these regulations applicable to Department-funded research and is not applicable to any research in an exempt category listed in § 46.101.

(2) Designation of one or more IRBs established in accordance with the requirements of this subpart, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the Secretary.[1]

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; (iii) for insuring prompt reporting to the IRB of proposed changes in a research activity, and for insuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subject; and (iv)

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[1] Reports should be filed with the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland 20205.

for insuring prompt reporting to the IRB and to the Secretary[1] of unanticipated problems involving risks to subjects or others.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by these regulations, and shall be filed in such form and manner as the Secretary may prescribe.

(d) The Secretary will evaluate all assurances submitted in accordance with these regulations through such officers and employees of the Department and such experts or consultants engaged for this purpose as the Secretary determines to be appropriate. The Secretary's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the Secretary may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The Secretary may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Within 60 days after the date of submission to HHS of an application or proposal, an institution with an approved assurance covering the proposed research shall certify that the application or proposal has been reviewed and approved by the IRB. Other institutions shall certify that the application or proposal has been approved by the IRB within 30 days after receipt of a request for such a certification from the Department. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

§§ 46.104—46.106 [Reserved]

§ 46.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, including but not limited to subjects covered by other subparts of this part, the IRB shall include one or more individuals who are primarily concerned with the welfare of these subjects.

(b) No IRB may consist entirely or men or entirely of women, or entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in nonscientific areas; for example: lawyers, ethicists, members of the clergy.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participating in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 46.108 IRB functions and operations.

In order to fulfill the requirements of these regulations each IRB shall:

(a) Follow written procedures as provided in § 46.103(b)(4).

(b) Except when an expedited review procedure is used (see § 46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

(c) Be responsible for reporting to the appropriate institutional officials and the Secretary[1] any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB.

[46 FR 8386, Jan. 26, 1981; 46 FR 19195, Mar. 27, 1981]

§ 46.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with § 46.116. The IRB may require that information, in addition to that specifically mentioned in § 46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with § 46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

§ 46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary has established, and published in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, through periodic republication in the FEDERAL REGISTER.

(b) An IRB may review some or all of the research appearing on the list through an expedited review procedure, if the research involves no more than minimal risk. The IRB may also use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in § 46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

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[1] Reports should be filed with the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland 20205.

(d) The Secretary may restrict, suspend, or terminate an institution's or IRB's use of the expedited review procedure when necessary to protect the rights or welfare of subjects.

§ 46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by these regulations the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § 46.117.

(6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects.

(7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 46.112 Review by institution.

Research covered by these regulations that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 46.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Secretary.[1]

[46 FR 8386, Jan. 26, 1981; 46 FR 19195, Mar. 27, 1981]

§ 46.114 Cooperative research.

Cooperative research projects are those projects, normally supported through grants, contracts, or similar arrangements, which involve institutions in addition to the grantee or prime contractor (such as a contractor with the grantee, or a subcontractor with the prime contractor). In such instances, the grantee or prime contractor remains responsible to the Department for safeguarding the rights and welfare of human subjects. Also, when cooperating institutions conduct some or all of the research involving some or all of these subjects, each cooperating institution shall comply with these regulations as though it received funds for its participation in the project directly from the Department, except that in complying with these regulations institutions may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

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[1] Reports should be filed with the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland 20205.

§ 46.115 IRB records.

(a) An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members as required by § 46.103(b)(3).

(6) Written procedures for the IRB as required by § 46.103(b)(4).

(7) Statements of significant new findings provided to subjects, as required by § 46.116(b)(5).

(b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Department at reasonable times and in a reasonable manner.

[46 FR 8386, Jan. 26, 1981; 46 FR 19195, Mar. 27, 1981]

§ 46.116 General requirements for informed consent.

Except as provided elsewhere in this or other subparts, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) Programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in these regulations are not intended to preempt any applicable Federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or local law.

[46 FR 8386, Jan. 26, 1981; 46 FR 29883, June 3, 1981, as amended at 48 FR 9270, Mar. 4, 1983]

§ 46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A "short form" written consent document stating that the elements of informed consent required by § 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the "short form."

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

§ 46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to the Department with the knowledge that subjects may be involved within the period of funding, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants (including bloc grants) where selection of specific projects is the institution's responsibility; research training grants where the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research described in § 46.101(b), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in these regulations, and certification submitted to the Department.

§ 46.119 Research undertaken without the intention of involving human subjects.

In the event research (conducted or funded by the Department) is undertaken without the intention of involving human subjects, but it is later proposed to use human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in these regulations, a certification submitted to the Department, and final approval given to the proposed change by the Department.

§ 46.120 Evaluation and disposition of applications and proposals.

(a) The Secretary will evaluate all applications and proposals involving human subjects submitted to the Department through such officers and employees of the Department and such experts and consultants as the Secretary determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the proposed research to the subjects and others, and the importance of the knowledge to be gained.

(b) On the basis of this evaluation, the Secretary may approve or disapprove the application or proposal, or enter into negotations to develop an approvable one.

§ 46.121 Investigational new drug or device 30-day delay requirement.

When an institution is required to prepare or to submit a certification with an application or proposal under these regulations, and the application or proposal involves an investigational new drug (within the meaning of 21 U.S.C. 355(i) or 357(d)) or a significant risk device (as defined in 21 CFR 812.3(m)), the institution shall identify the drug or device in the certification. The institution shall also state whether the 30-day interval required for investigational new drugs by 21 CFR 312.1(a) and for significant risk devices by 21 CFR 812.30 has elapsed, or whether the Food and Drug Administration has waived that requirement. If the 30-day interval has expired, the institution shall state whether the Food and Drug Administration has requested that the sponsor continue to withhold or restrict the use of the drug or device in human subjects. If the 30-day interval has not expired, and a waiver has not been received, the institution shall send a statement to the Department upon expiration of the interval. The Department will not consider a certification acceptable until the institution has submitted a statement that the 30-day interval has elapsed, and the Food and Drug Administration has not requested it to limit the use of the drug or device, or that the Food and Drug Administration has waived the 30-day interval.

§ 46.122 Use of Federal funds.

Federal funds administered by the Department may not be expended for research involving human subjects unless the requirements of these regulations, including all subparts of these regulations, have been satisfied.

§ 46.123 Early termination of research funding; evaluation of subsequent applications and proposals.

(a) The Secretary may require that Department funding for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the Secretary finds an institution has materially failed to comply with the terms of these regulations.

(b) In making decisions about funding applications or proposals covered by these regulations the Secretary may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person who would direct the scientific and technical aspects of an activity has in the judgment of the Secretary materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not Department funds were involved).

§ 46.124 Conditions.

With respect to any research project or any class of research projects the Secretary may impose additional conditions prior to or at the time of funding when in the Secretary's judgment additional conditions are necessary for the protection of human subjects.

Subpart B—Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization

SOURCE: 40 FR 33528, Aug. 8, 1975, unless otherwise noted.

§ 46.201 Applicability.

(a) The regulations in this subpart are applicable to all Department of Health and Human Services grants and contracts supporting research, development, and related activities involving: (1) The fetus, (2) pregnant women, and (3) human *in vitro* fertilization.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.202 Purpose.

It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.

§ 46.203 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) "Pregnancy" encompasses the period of time from confirmation of implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.

(c) "Fetus" means the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until a determination is made, following expulsion or extraction of the fetus, that it is viable.

(d) "Viable" as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the FEDERAL REGISTER guidelines to assist in determining whether a fetus is viable for purposes of this subpart. If a fetus is viable after delivery, it is a premature infant.

(e) "Nonviable fetus" means a fetus *ex utero* which, although living, is not viable.

(f) "Dead fetus" means a fetus *ex utero* which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).

(g) *"In vitro* fertilization" means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

[40 FR 33528, Aug. 8, 1975, as amended at 4 FR 1759, Jan. 11, 1978]

§ 46.204 Ethical Advisory Boards.

(a) One or more Ethical Advisory Boards shall be established by the Secretary. Members of these board(s) shall be so selected that the board(s) will be competent to deal with medical, legal, social, ethical, and related issues and may include, for example, research scientists, physicians, psychologists, sociologists, educators, lawyers, and ethicists, as well as representatives of the general public. No board member may be a regular, full-time employee of the Department of Health and Human Services.

(b) At the request of the Secretary, the Ethical Advisory Board shall render advice consistent with the policies and requirements of this part as to ethical issues, involving activities covered by this subpart, raised by individual applications or proposals. In addition, upon request by the Secretary, the Board shall render advice as to classes of applications or proposals and general policies, guidelines, and procedures.

(c) A Board may establish, with the approval of the Secretary, classes of applications or proposals which: (1) Must be submitted to the Board, or (2) need not be submitted to the Board.

where the Board so establishes a class of applications or proposals which must be submitted, no application or proposal within the class may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

(d) No application or proposal involving human *in vitro* fertilization may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

[40 FR 33528, Aug. 8, 1975, as amended at 43 FR 1759, Jan. 11, 1978]

§ 46.205 Additional duties of the Institutional Review Boards in connection with activities involving fetuses, pregnant women, or human in vitro fertilization.

(a) In addition to the responsibilities prescribed for Institutional Review Boards under Subpart A of this part, the applicant's or offeror's Board shall, with respect to activities covered by this subpart, carry out the following additional duties:

(1) Determine that all aspects of the activity meet the requirements of this subpart;

(2) Determine that adequate consideration has been given to the manner in which potential subjects will be selected, and adequate provision has been made by the applicant or offeror for monitoring the actual informed consent process (e.g., through such mechanisms, when appropriate, as participation by the Institutional Review Board or subject advocates in: (i) Overseeing the actual process by which individual consents required by this subpart are secured either by approving induction of each individual into the activity or verifying, perhaps through sampling, that approved procedures for induction of individuals into the activity are being followed, and (ii) monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen);

(3) Carry out such other responsibilities as may be assigned by the Secretary.

(b) No award may be issued until the applicant or offeror has certified to the Secretary that the Institutional Review Board has made the determinations required under paragraph (a) of this section and the Secretary has approved these determinations, as provided in § 46.120 of Subpart A of this part.

(c) Applicants or offerors seeking support for activities covered by this subpart must provide for the designation of an Institutional Review Board, subject to approval by the Secretary, where no such Board has been established under Subpart A of this part.

[40 FR 33528, Aug. 8, 1975, as amended at 46 FR 8386, Jan. 26, 1981]

§ 46.206 General limitations.

(a) No activity to which this subpart is applicable may be undertaken unless:

(1) Appropriate studies on animals and nonpregnant individuals have been completed;

(2) Except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity.

(3) Individuals engaged in the activity will have no part in: (i) Any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (ii) determining the viability of the fetus at the termination of the pregnancy; and

(4) No procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.

(b) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

[40 FR 33528, Aug. 8, 1975, as amended at 40 FR 51638, Nov. 6, 1975]

§ 46.207 Activities directed toward pregnant women as subjects.

(a) No pregnant woman may be involved as a subject in an activity covered by this subpart unless: (1) The purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (1) The purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape.

§ 46.208 Activities directed toward fetuses in utero as subjects.

(a) No fetus *in utero* may be involved as a subject in any activity covered by this subpart unless: (1) The purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if: (1) His identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

§ 46.209 Activities directed toward fetuses ex utero, including nonviable fetuses, as subjects.

(a) Until it has been ascertained whether or not a fetus ex utero is viable, a fetus ex utero may not be involved as a subject in an activity covered by this subpart unless:

(1) There will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or

(2) The purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

(b) No nonviable fetus may be involved as a subject in an activity covered by this subpart unless:

(1) Vital functions of the fetus will not be artificially maintained,

(2) Experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and

(3) The purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(c) In the event the fetus *ex utero* is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other subparts of this part.

(d) An activity permitted under paragraph (a) or (b) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if: (1) His identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

[40 FR 33528, Aug. 8, 1975, as amended at 4 FR 1759, Jan. 11, 1978]

§ 46.210 Activities involving the dead fetus, fetal material, or the placenta.

Activities involving the dead fetus, mascerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable State or local laws regarding such activities.

§ 46.211 Modification or waiver of specific requirements.

Upon the request of an applicant or offeror (with the approval of its Institutional Review Board), the Secretary may modify or waive specific requirements of this subpart, with the approval of the Ethical Advisory Board after such opportunity for public comment as the Ethical Advisory Board considers appropriate in the particular instance. In making such decisions, the Secretary will consider whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver. Any such modifications or waivers will be published as notices in the FEDERAL REGISTER.

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

SOURCE: 43 FR 53655, Nov. 16, 1978, unless otherwise noted.

§ 46.301 Applicability.

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.302 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§ 46.303 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) "DHHS" means the Department of Health and Human Services.

(c) "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) "Minimal risk" is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

§ 46.304 Composition of Institutional Review Boards where prisoners are involved.

In addition to satisfying the requirements in § 46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

[43 FR 53655, Nov. 16, 1978, as amended at 46 FR 8386, Jan. 26, 1981]

§ 46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

(1) The research under review represents one of the categories of research permissible under § 46.306(a)(2);

(2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) The information is presented in language which is understandable to the subject population;

(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§ 46.306 Permitted research involving prisoners.

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under § 46.305 of this subpart; and

(2) In the judgment of the Secretary the proposed research involves solely the following:

(i) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(ii) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or

(iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

Subpart D—Additional Protections for Children Involved as Subjects in Research

SOURCE: 48 FR 9818, Mar. 8, 1983, unless otherwise noted.

§ 46.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of § 46.101 of Subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions (1), (2), (5) and (6) as listed in Subpart A at § 46.101(b) are applicable to this subpart. Exemption (4), research involving the observation of public behavior, listed at § 46.101(b), is applicable to this subpart where the investigator(s) does not participate in the activities being observed. Exemption (3), research involving survey or interview procedures, listed at § 46.101(b) does not apply to research covered by this subpart.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of § 46.101 of Subpart A are applicable to this subpart.

§ 46.402 Definitions.

The definitions in § 46.102 of Subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) "Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) "Parent" means a child's biological or adoptive parent.

(e) "Guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

§ 46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§ 46.404 Research not involving greater than minimal risk.

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in § 46.408.

§ 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) The risk represents a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

HHS will conduct or fund research that the IRB does not believe meets the requirements of § 46.404, § 46.405, or § 46.406 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either: (1) That the research in fact satisfies the conditions of § 46.404, § 46.405, or § 46.406, as applicable, or (2) the following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) The research will be conducted in accordance with sound ethical principles;

(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in § 46.408.

§ 46.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with § 46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by § 46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under § 46.404 or § 46.405. Where research is covered by §§ 46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in § 46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by § 46.117 of Subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§ 46.409 Wards.

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under § 46.406 or § 46.407 only if such research is:

(1) Related to their status as wards; or

(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

PART 50—U.S. EXCHANGE VISITOR PROGRAM—REQUEST FOR WAIVER OF THE TWO-YEAR FOREIGN RESIDENCE REQUIREMENT

Sec.

50.1 Authority.
50.2 Exchange Visitor Waiver Review Board.
50.3 Policy.
50.4 Procedures for submission of application to HHS.
50.5 Personal hardship, persecution and visa extension considerations.
50.6 Release from foreign government.

AUTHORITY: 75 Stat. 527 (22 U.S.C. 2451 et seq.); 84 Stat. 116 (8 U.S.C. 1182(e)).

SOURCE: 49 FR 9900, Mar. 16, 1984, unless otherwise noted.

§ 50.1 Authority.

Under the authority of Mutual Educational and Cultural Exchange Act of 1961 (75 Stat. 527) and the Immigration and Nationality Act as amended (84 Stat. 116), the Department of Health and Human Services is an "interested United States Government agency" with the authority to request the United States Information Agency to recommend to the Attorney General waiver of the two-year foreign residence requirement for exchange visitors under the Mutual Educational and Cultural Exchange Program.

§ 50.2 Exchange Visitor Waiver Review Board.

(a) *Establishment.* The Exchange Visitor Waiver Review Board is established to carry out the Department's responsibilities under the Exchange Visitor Program.

(b) *Functions.* The Exchange Visitor Waiver Review Board is responsible for making thorough and equitable evaluations of applications submitted by institutions, acting on behalf of exchange visitors, to the Department of HHS for a favorable recommendation to the United States Information Agency that the two-year foreign residence requirement for exchange visitors under the Exchanges Visitor Program be waived.

(c) *Membership.* The Exchange Visitor Waiver Review Board consists of no fewer than three members and two alternates, of whom no fewer than three shall consider any particular application. The Director of the Office of International Affairs, Office of the Secretary, is an ex officio member of the Board and serves as its Chairman. The Director may designate a staff member of the Office of the Secretary to serve as member and Chairman of the Board in the Director's absence. Two regularly assigned members and two alternates are appointed by the Assistant Secretary of Health to consider applications concerning health, biomedical research, and related fields. The Chairman may request the heads of operating divisions of the Department to appoint additional members to consider applications in other fields of interest to the Department (e.g. human services, social security). The Board may obtain expert advisory opinions from other sources.

(d) *Eligibility.* The Board will review applications submitted by private or non-federal institutions, organizations or agencies or by a component agency of HHS. The Board will not consider applications submitted by exchange visitors or, unless under extenuating and exceptional circumstances, other U.S. Government Agencies.

§ 50.3 Policy.

(a) *Criteria and information pertaining to waivers.* The Department of Health and Human Services endorses the philosophy of the Exchange Visitor Program that exchange visitors are committed to return home for at least two years after completing their program. This requirement was imposed to prevent the Program from becoming a stepping stone to immigration and to insure that exchange visitors make their new knowledge and skills available to their home countries. Accordingly, the Board carefully applies stringent and restrictive criteria to its consideration of requests that it support waivers for exchange visitors. Each application is evaluated individually on the basis of the facts available.

In determining whether to recommend an exemption for an exchange visitor from his/her obligation to the Exchange Visitor Program, the Board considers the following key factors:

(1) The program or activity at the applicant institution or organization in which the exchange visitor is employed must be of high priority and of national or international significance in an area of interest to the Department. The Board will not request a waiver when the application demonstrates that the exchange visitor is needed merely to provide services for a limited geographical area and/or to alleviate a local community or institutional manpower shortage, however serious.

(2) The exchange visitor must be needed as an integral part of the program or activity, or of an essential component thereof, so that loss of his/her services would necessitate discontinuance of the program, or a major phase of it. *Specific evidence* must be provided as to how the loss or unavailability of the individual's services would adversely affect the initiation, continuance, completion, or success of the program or activity. The applicant organization/institution must clearly demonstrate that a suitable replacement for the exchange visitor cannot be found through recruitment or any other means. The Board will not request a waiver when the principal problem appears to be one of administrative, budgetary, or program inconvenience to the institution or other employer.

(3) The exchange visitor must possess outstanding qualifications, training and experience well beyond the usually expected accomplishments at the graduate, postgraduate, and residency levels, and must clearly demonstrate the capability to make original and significant contributions to the program. The Board will not request a waiver simply because an individual has specialized training or experience or is occupying a senior staff position in a university, hospital, or other institution.

(b) *Waiver for members of exchange visitor's family.* Where a decision is made to request a waiver for an exchange visitor, a waiver will also be requested for the spouse and children, if any, if they have J-2 visa status. When both members of a married couple are exchange visitors in their own right (i.e., each has J-1 visa status), separate applications must be submitted for each of them.

§ 50.4 Procedures for submission of application to HHS.

(a) The applicant institution (educational institution, hospital, laboratory, corporation, etc.) should send a completed application (HHS Form 426; O.M.B. No. 0990-0001) to the Executive Secretary, Exchange Visitor Waiver Review Board, Room 655-G, Humphrey Building, Department of Health and Human Services, 200 Independence Avenue, S.W., Washington, D.C. 20201. Application forms, instruction sheets, and information may be obtained from the Executive Secretary (202/245-6174). The application must be filled out completely and signed by an authorized official of the applicant institution. The application and accompanying materials should include information that describes in detail the circumstances of the case involved.

(b) Since the formal filing of an application for waiver with the Immigration and Naturalization Service automatically terminates the applicant's exchange visitor status, it is permissible to obtain the decision of the Exchange Visitor Waiver Review Board before filing with the Immigration and Naturalization Service.

§ 50.5 Personal hardship, persecution and visa extension considerations.

(a) It is *not* within the Department's jurisdiction to consider applications for waiver based on:

(1) Exceptional hardship to the exchange visitor's American or legally resident alien spouse or child; or

(2) The alien's unwillingness to return to the country of his/her nationality or last residence on the grounds that he/she or family members would be subject to persecution on account of race, religion or political opinion.

(b) Likewise, this Department is not responsible for considering requests to extend visas.

(c) Inquiries concerning the above should be directed to the District Office of the Immigration and Naturalization Service which has jurisdiction over the exchange visitor's place of residence in the United States.

§ 50.6 Release from foreign government.

The United States Information Agency has the responsibility to consider applications for waivers that are based solely on a notification from the exchange visitor's country that it has no objection to a waiver (22 CFR 63.31).

PART 51—CRITERIA FOR EVALUATING COMPREHENSIVE PLAN TO REDUCE RELIANCE ON ALIEN PHYSICIANS

Sec.
51.1 Purpose.
51.2 Application.
51.3 Who is eligible to apply?
51.4 How will the plans be evaluated?

AUTHORITY: Sec. 212, Immigration and Nationality Act, Pub. L. 82-114, as amended by Pub. L. 97-116, 95 Stat. 1611 (8 U.S.C. 1182(j)(2)(A)).

SOURCE: 48 FR 2539, Jan. 20, 1983, unless otherwise noted.

§ 51.1 Purpose.

The purpose of this regulation is to establish criteria for review and evaluation of the comprehensive plans of Graduate Medical Education Programs to reduce reliance on alien physicians, as required by the Immigration and Nationality Act Amendments of 1981, Pub. L. 97-116, for the waiver of certain requirements for exchange visitors who are coming to the United States to participate in programs of graduate medical education or training.

§ 51.2 Application.

Materials covering procedures for applying for substantial disruption waivers (including the comprehensive plan) may be obtained from the Educational Commission for Foreign Medical Graduates, 3624 Market Street, Philadelphia, Pennsylvania 19104.

EXPLANATORY NOTE: The Department of State entered into an agreement with the Educational Commission for Foreign Medical Graduates in 1971 whereby the latter was designated the authority to administer the issuance of the Form IAP-66 in all cases involving the admission, certification, transfer or extension of stay for foreign physicians in exchange visitor status who are receiving graduate medical education or training. The Commission was further designated the authority (FEDERAL REGISTER, Volume 44, No. 59, March 26, 1979), to process waiver requests under the "substantial disruption" provision of Pub. L. 94-484, as amended, within criteria to be provided by the United States Information Agency on advice from the Department of Health and Human Services (formerly Department of Health, Education, and Welfare).

§ 51.3 Who is eligible to apply?

Sponsors which had alien physicia in their exchange visitor programs o January 10, 1978, are eligible to appl For purposes of this regulation, th term "program" relates to a graduat medical education program having a exchange visitor program for physi cians participating in graduate medic education or training. An "exchang visitor program" is a program of sponsor, designed to promote inte change of persons, knowledge an skills, and the interchange of develop ments in the field of education, th arts and sciences, and is concerne with one or more categories of partic pants to promote mutual understand ing between the people of the Unite States and the people of other countries.

§ 51.4 How will the plans be evaluated?

After consultation with the Feder Substantial Disruption Waiver Boar (seven Federal representatives charge with the responsibility of reviewin substantial disruption waiver applic tions), the Secretary of Health an Human Services will make recommen dations to the Director, United State Information Agency, for the purpos of granting waivers. The Secretary wil consider the following factors in determining whether or not a plan is satisfactory:

(a) The extent of the specific problems that the program or institutio anticipates without a waiver, including, for example,

(1) Curtailment of services currentl provided,

(2) Downgrading of medical care currently being provided,

(3) Reduction in the number of inpatients and outpatients receiving care,

(4) Inadequate medical coverage fo population served, or

(5) Inadequate supervision of junio residents.

(b) The adequacy of the alternativ resources and methods (including us of physician assistants (as defined i 42 CFR 57.802), nurse practitioners (a defined in 42 CFR 57.2402), and othe non-physician providers) that hav been considered and have been an will be applied to reduce such disrup tion in the delivery of health services, especially in primary medical care manpower shortage areas, as established under section 332 of the Public Health Service Act, and for medicaid patients. This may include, for example:

(1) Greater reliance on fully licensed physicians, and on physician assistants, nurse practitioners and other non-physician personnel in an expanded role in the delivery of health care, such as admission patient histories, making patient rounds, recording patient progress notes, doing the initial and follow-up evaluation of patients, performing routine laboratory and related studies, or

(2) Utilization of the team approach to health care delivery (individuals functioning as an integral part of an interprofessional team of health personnel organized under the leadership of a physician working toward more efficient and/or more effective delivery of health services).

(c) The extent to which changes (including improvement of educational and medical services) have been considered and which have been or will be applied to make the program more attractive to graduates of medical schools who are citizens of the United States, as demonstrated, for example, by:

(1) Adding additional services to the existing programs to provide a broader educational experience for residents,

(2) Expanding affiliations with other residency programs to offer a broader experience for residents,

(3) Expanding undergraduate clerkships to provide a broader educational experience.

(4) Creating or modifying administrative units which will provide broader clinical experiences, or

(5) Initiating research projects.

(d) The adequacy of the recruitment efforts which have been and will be undertaken to attract graduates of medical schools who are citizens of the United States, as demonstrated, for example, by:

(1) Broad-based advertisement of the program and of the institution through notices in journals, contacts with medical schools, etc.

(2) Forming committees for the purpose of recruiting U.S. citizens.

(3) Working with national organizations which are involved with medical students and U.S. graduate medical trainees, e.g., the American Medical Student Association and the Physician National House Staff Association, to attract U.S. citizens.

(e) The extent to which the program on a year-by-year basis has phased down its dependence upon aliens who are graduates of foreign medical schools so that the program will not be dependent upon the admission to the program of any additional such aliens after December 31, 1983.

PART 57—VOLUNTEER SERVICES

Sec.
57.1 Applicability.
57.2 Definitions.
57.3 Volunteer service programs.
57.4 Acceptance and use of volunteer services.
57.5 Services and benefits available to volunteers.

Authority: Sec. 223, 58 Stat. 683, as amended by 81 Stat. 539: 42 U.S.C. 217b.

Source: 34 FR 13868, Aug. 29, 1969, unless otherwise noted.

§ 57.1 Applicability.

The regulations in this part apply to the acceptance of volunteer and uncompensated services for use in the operation of any health care facility of the Department or in the provision of health care.

§ 57.2 Definitions.

As used in the regulations in this part:

"*Secretary*" means the Secretary of Health and Human Services.

"*Department*" means the Department of Health and Human Services.

"*Volunteer services*" are services performed by individuals (hereafter called volunteers) whose services have been offered to the Government and accepted under a formal agreement on a without compensation basis for use in the operation of a health care facility or in the provision of health care.

"*Health care*" means services to patients in Department facilities, beneficiaries of the Federal Government, or individuals or groups for whom health services are authorized under the programs of the Department.

"Health care facility" means a hospital, clinic, health center, or other facility established for the purpose of providing health care.

§ 57.3 Volunteer service programs.

Programs for the use of volunteer services may be established by the Secretary, or his designe, to broaden and strengthen the delivery of health services, contribute to the comfort andwell being of patients in Department hospitals or clinics, or expand the services required in the operation of a health care facility. Volunteers may be used to supplement, but not to take the place of, personnel whose services are obtained through the usual employment procedures.

§ 57.4 Acceptance and use of volunteer services.

The Secretary, or his designee, shall establish requirements for: Accepting volunteer services from individuals or groups of individuals, using volunteer services, giving appropriate recognition to volunteers, and maintaining records of volunteer services.

§ 57.5 Services and benefits available to volunteers.

(a) The following provisions of law may be applicable to volunteers whose services are offered and accepted under the regulations in this part:

(1) Subchapter I of Chapter 81 of Title 5 of the United States Code relating to medical services for work related injuries;

(2) Title 28 of the United States Code relating to tort claims;

(3) Section 7903 of Title 5 of the United States Code relating to protective clothing and equipment; and

(4) Section 5703 of Title 5 of the United States Code relating to travel and transportation expenses.

(b) Volunteers may also be provided such other benefits as are authorized by law or by administrative action of the Secretary or his designee.

PART 60—NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS AND OTHER HEALTH CARE PRACTITIONERS

Subpart A—General Provisions

Sec.
60.1 The National Practitioner Data Bank.
60.2 Applicability of these regulations.
60.3 Definitions.

Subpart B—Reporting of information.

60.4 How information must be reported.
60.5 When information must be reported.
60.6 Reporting errors, omissions, and revisions.
60.7 Reporting medical malpractice payments.
60.8 Reporting licensure actions taken by Boards of Medical Examiners.
60.9 Reporting adverse actions on clinical privileges.

Subpart C—Disclosure of information by the National Practitioner Data Bank.

60.10 Information which hospitals must request from the National Practitioner Data Bank.
60.11 Requesting information from the National Practitioner Data Bank.
60.12 Fees applicable to requests for information.
60.13 Confidentiality of National Practitioner Data Bank information.
60.14 How to dispute the accuracy of National Practitioner Data Bank information.

AUTHORITY: Secs. 401–432 of the Health Care Quality Improvement Act of 1986, Pub. L. 99–660, 100 Stat. 3784–3794, as amended by section 402 of Pub. L. 100-177, 101 Stat. 1007–1008 (42 U.S.C. 11101–11152).

SOURCE:: 54 FR 42730, Oct. 17, 1989, unless otherwise noted.

EFFECTIVE DATE NOTE: At 54 FR 42730, Oct. 17, 1989, Part 60 was added to be effective on the date on which the National Practitioner Data Bank is operational. The Secretary will publish this date in an announcement in the Federal Register.

Subpart A—General Provisions

§ 60.1 The National Practitioner Data Bank.

The Health Care Quality Improvement Act of 1986 (the Act), title IV of Pub. L. 99–660, as amended, authorizes the Secretary to establish (either directly or by contract) a National Practitioner Data Bank to collect and release certain information relating to the professional competence and conduct of physicians, dentists and other health care practitioners. These regulations set forth the reporting and disclosure requirements for the National Practitioner Data Bank.

§ 60.2 Applicability of these regulations.

These regulations establish reporting requirements applicable to hospitals; health care entities; Boards of Medical Examiners; professional societies of physicians, dentists or other health care practitioners which take adverse licensure or professional review actions; and individuals and entities (including insurance companies) making payments as a result of medical malpractice actions or claims. They also establish procedures to enable individuals or entities to obtain information from the National Practitioner Data Bank or to dispute the accuracy of National Practitioner Data Bank information.

§ 60.3 Definitions.

Act means the Health Care Quality Improvement Act of 1986, title IV of Pub. L. 99-660, as amended.

Adversely affecting means reducing, restricting, suspending, revoking, or denying clinical privileges or membership in a health care entity.

Board of Medical Examiners, or "Board," means a body or subdivision of such body which is designated by a State for the purpose of licensing, monitoring and disciplining physicians or dentists. This term includes a Board of Osteopathic Examiners or its subdivision, a Board of Dentistry or its subdivision, or an equivalent body as determined by the State. Where the Secretary, pursuant to section 423(c)(2) of the Act, has designated an alternate entity to carry out the reporting activities of § 60.9 due to a Board's failure to comply with § 60.5, the term "Board of Medical Examiners" or "Board" refers to this alternate entity.

Clinical privileges means the authorization by a health care entity to a physician, dentist or other health care practitioner for the provision of health care services, including privileges and membership on the medical staff.

Dentist means a doctor of dental surgery, doctor of dental medicine, or the equivalent who is legally authorized to practice dentistry by a State (or who, without authority, holds himself or herself out to be so authorized).

Formal peer review process means the conduct of professional review activities through formally adopted written procedures which provide for adequate notice and an opportunity for a hearing.

Health care entity means:

(a) A hospital;

(b) An entity that provides health care services, and engages in professional review activity through a formal peer review process for the purpose of furthering quality health care, or a committee of that entity; or

(c) A professional society or a committee or agent thereof, including those at the national, State, or local level, of physicians, dentists, or other health care practitioners that engages in professional review activity through a formal peer review process, for the purpose of furthering quality health care.

For purposes of paragraph (b) of this definition, an entity includes: a health maintenance organization which is licensed by a State or determined to be qualified as such by the Department of Health and Human Services; and any group or prepaid medical or dental practice which meets the criteria of paragraph (b).

Health care practitioner means an individual other than a physician or dentist, who is licensed or otherwise authorized by a State to provide health care services.

Hospital means an entity described in paragraphs (1) and (7) of section 1861(e) of the Social Security Act.

Medical malpractice action or claim means a written complaint or claim demanding payment based on a physician's, dentists or other health care practitioner's provision of or failure to provide health care services, and includes the filing of a cause of action based on the law of tort, brought in any State or Federal Court or other adjudicative body.

Physician means a doctor of medicine or osteopathy legally authorized to practice medicine or surgery by a

State (or who, without authority, holds himself or herself out to be so authorized).

Professional review action means an action or recommendation of a health care entity:

(a) Taken in the course of professional review activity;

(b) Based on the professional competence or professional conduct of an individual physician, dentist or other health care practitioner which affects or could affect adversely the health or welfare of a patient or patients; and

(c) Which adversely affects or may adversely affect the clinical privileges or membership in a professional society of the physician, dentist or other health care practitioner.

(d) This term excludes actions which are primarily based on:

(1) The physician's, dentist's or other health care practitioner's association, or lack of association, with a professional society or association;

(2) The physician's, dentist's or other health care practitioner's fees or the physician's, dentist's or other health care practitioner's advertising or engaging in other competitive acts intended to solicit or retain business;

(3) The physician's, dentist's or other health care practitioner's participation in prepaid group health plans, salaried employment, or any other manner of delivering health services whether on a fee-for-service or other basis;

(4) A physician's, dentist's or other health care practitioner's association with, supervision of, delegation of authority to, support for, training of, or participation in a private group practice with, a member or members of a particular class of health care practitioner or professional; or

(5) Any other matter that does not relate to the competence or professional conduct of a physician, dentist or other health care practitioner.

Professional review activity means an activity of a health care entity with respect to an individual physician, dentist or other health care practitioner:

(a) To determine whether the physician, dentist or other health care practitioner may have clinical privileges with respect to, or membership in, the entity;

(b) To determine the scope or conditions of such privileges or membership; or

(c) To change or modify such privileges or membership.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

State means the fifty States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

[54 FR 42730, Oct. 17, 1989; 54 FR 43890, Oct. 27, 1989]

Subpart B—Reporting of Information

§ 60.4 How information must be reported.

Information must be reported to the Data Bank or to a Board of Medical Examiners as required under §§ 60.7, 60.8, and 60.9 in such form and manner as the Secretary may prescribe.

§ 60.5 When information must be reported.

Information required under §§ 60.7, 60.8, and 60.9 must be submitted to the Data Bank within 30 days following the action to be reported, beginning with actions occurring on or after the effective date of these regulations or the date of the establishment of the Data Bank, whichever is later, as follows:

(a) *Malpractice Payments* (*§ 60.7*). Persons or entities must submit information to the Data Bank within 30 days from the date that a payment, as described in § 60.7, is made. If required under § 60.7, this information must be submitted simultaneously to the appropriate State licensing board.

(b) *Licensure Actions* (*§ 60.8*). The Board must submit information within 30 days from the date the licensure action was taken.

(c) *Adverse Actions* (*§ 60.9*). A health care entity must report an adverse action to the Board within 15 days from the date the adverse action was taken. The Board must submit the information received from a health care entity within 15 days from the date on which it received this information. If required under § 60.9, this information must be submitted by the Board simultaneously to the appropriate State licensing board in the State in which the health care entity is located, if the Board is not such licensing Board.

§ 60.6 Reporting errors, omissions, and revisions.

(a) Persons and entities are responsible for the accuracy of information which they report to the Data Bank. If errors or omissions are found after information has been reported, the person or entity which reported it must send an addition or correction to the Data Bank or, in the case of reports made under § 60.9, to the Board of Medical Examiners, as soon as possible.

(b) An individual or entity which reports information on licensure or clinical privileges under §§ 60.8 or 60.9 must also report any revision of the action originally reported. Revisions include reversal of a professional review action or reinstatement of a license. Revisions are subject to the same time constraints and procedures of §§ 60.5, 60.8, and 60.9, as applicable to the original action which was reported.

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§ 60.7 Reporting medical malpractice payments.

(a) *Who must report.* Each person or entity, including an insurance company, which makes a payment under an insurance policy, self-insurance, or otherwise, for the benefit of a physician, dentist or other health care practitioner in settlement of or in satisfaction in whole or in part of a claim or a judgment against such physician, dentist, or other health care practitioner for medical malpractice, must report information as set forth in paragraph (b) to the Data Bank and to the appropriate State licensing board(s) in the State in which the act or omission upon which the medical malpractice claim was based. For purposes of this section, the waiver of an outstanding debt is not construed as a "payment" and is not required to be reported.

(b) *What information must be reported.* Persons or entities described in paragraph (a) must report the following information:

(1) With respect to the physician, dentist or other health care practitioner for whose benefit the payment is made—

(i) Name,

(ii) Work address,

(iii) Home address, if known,

(iv) Social Security number, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974,

(v) Date of birth,

(vi) Name of each professional school attended and year of graduation,

(vii) For each professional license: the license number, the field of licensure, and the name of the State or Territory in which the license is held,

(viii) Drug Enforcement Administration registration number, if known,

(ix) Name of each hospital with which he or she is affiliated, if known;

(2) With respect to the reporting person or entity—

(i) Name and address of the person or entity making the payment,

(ii) Name, title, and telephone number of the responsible official submitting the report on behalf of the entity, and

(iii) Relationship of the reporting person or entity to the physician, dentist, or other health care practitioner for whose benefit the payment is made;

(3) With respect to the judgment or settlement resulting in the payment—

(i) Where an action or claim has been filed with an adjudicative body, identification of the adjudicative body and the case number,

(ii) Date or dates on which the act(s) or omission(s) which gave rise to the action or claim occurred,

(iii) Date of judgment or settlement,

(iv) Amount paid, date of payment, and whether payment is for a judgment or a settlement,

(v) Description and amount of judgment or settlement and any conditions attached thereto, including terms of payment,

(vi) A description of the acts or omissions and injuries or illnesses upon which the action or claim was based,

(vii) Classification of the acts or omissions in accordance with a reporting code adopted by the Secretary, and

(viii) Other information as required by the Secretary from time to time after publication in the FEDERAL REGISTER and after an opportunity for public comment.

(c) *Sanctions.* Any person or entity that fails to report information on a payment required to be reported under this section is subject to a civil money penalty of up to $10,000 for each such payment involved. This penalty will be imposed pursuant to procedures at 42 CFR part 1003.

(d) *Interpretation of information.* A payment in settlement of a medical malpractice action or claim shall not be construed as creating a presumption that medical malpractice has occurred.

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§ 60.8 Reporting licensure actions taken by Boards of Medical Examiners.

(a) *What actions must be reported.* Each Board of Medical Examiners must report to the Data Bank any action based on reasons relating to a physician's or dentist's professional competence or professional conduct–

(1) Which revokes or suspends (or otherwise restricts) a physician's or dentist's license,

(2) Which censures, reprimands, or places on probation a physician or dentist, or

(3) Under which a physician's or dentist's license is surrendered.

(b) *Information that must be reported.* The Board must report the following information for each action:

(1) The physician's or dentist's name,

(2) The physician's or dentist's work address,

(3) The physician's or dentist's home address, if known,

(4) The physician's or dentist's Social Security number, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974,

(5) The physician's or dentist's date of birth,

(6) Name of each professional school attended by the physician or dentist and year of graduation,

(7) For each professional license, the physician's or dentist's license number, the field of licensure and the name of the State or Territory in which the license is held,

(8) The physician's or dentist's Drug Enforcement Administration registration number, if known,

(9) A description of the acts or omissions or other reasons for the action taken,

(10) A description of the Board action, the date the action was taken, and its effective date,

(11) Classification of the action in accordance with a reporting code adopted by the Secretary, and

(12) Other information as required by the Secretary from time to time after publication in the FEDERAL REGISTER and after an opportunity for public comment.

(c) *Sanctions.* If, after notice of noncompliance and providing opportunity to correct noncompliance, the Secretary determines that a Board has failed to submit a report as required by this section, the Secretary will designate another qualified entity for the reporting of information under § 60.9.

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§ 60.9 Reporting adverse actions on clinical privileges.

(a) *Reporting to the Board of Medical Examiners.*—(1) *Actions that must be reported and to whom the report must be made.* Each health care entity must report to the Board of Medical Examiners in the State in which the health care entity is located the following actions:

(i) Any professional review action that adversely affects the clinical privileges of a physician or dentist for a period longer than 30 days;

(ii) Acceptance of the surrender of clinical privileges or any restriction of such privileges by a physician or dentist—

(A) While the physician or dentist is under investigation by the health care entity relating to possible incompetence or improper professional conduct, or

(B) In return for not conducting such an investigation or proceeding; or

(iii) In the case of a health care entity which is a professional society, when it takes a professional review action.

(2) *Voluntary reporting on other health care practitioners.* A health care entity may report to the Board of Medical Examiners information as described in paragraph (a)(3) of this section concerning actions described in paragraph (a)(1) in this section with respect to other health care practitioners.

(3) *What information must be reported.* The health care entity must report the following information concerning actions described in paragraph (a)(1) of this section with respect to the physician or dentist:

(i) Name,

(ii) Work address,

(iii) Home address, if known,

(iv) Social Security number, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974,

(v) Date of birth,

(vi) Name of each professional school attended and year of graduation,

(vii) For each professional license: the license number, the field of licensure, and the name of the State or Territory in which the license is held,

(viii) Drug Enforcement Administration registration number, if known,

(ix) A description of the acts or omissions or other reasons for privilege loss, or, if known, for surrender,

(x) Action taken, date the action was taken, and effective date of the action, and

(xi) Other information as required by the Secretary from time to time after publication in the FEDERAL REGISTER and after an opportunity for public comment.

(b) *Reporting by the Board of Medical Examiners to the National Practitioner Data Bank.* Each Board must report, in accordance with §§ 60.4 and 60.5, the information reported to it by a health care entity and any known instances of a health car entity's failure to report information as required under paragraph (a)(1) of this section. In addition, each Board must simultaneously report this information to the appropriate State licensing board in the State in which the health care entity is located, if the Board is not such licensing board.

(c) *Sanctions*—(1) *Health care entities.* If the Secretary has reason to believe that a health care entity has substantially failed to report information in accordance with § 60.9, the Secretary will conduct an investigation. If the investigation shows that the health care entity has not complied with § 60.9, the Secretary will provide the entity with a written notice describing the noncompliance, giving the health care entity an opportunity to correct the noncompliance, and stating that the entity may request, within 30 days after receipt of such notice, a hearing with respect to the noncompliance. The request for a hearing must contain a statement of the material factual issues in dispute to demonstrate that there is cause for a hearing. These issues must be both substantive and relevant. The hearing will be held in the Washington, DC, metropolitan area. The Secretary will deny a hearing if:

(i) The request for a hearing is untimely,

(ii) The health care entity does not provide a statement of material factual issues in dispute, or

(iii) The statement of factual issues in dispute is frivolous or inconsequential.

In the event that the Secretary denies a hearing, the Secretary will send a written denial to the health care entity setting forth the reasons for denial. If a hearing is denied, or if as a result of the hearing the entity is found to be in noncompliance, the Secretary will publish the name of the health care entity in the FEDERAL REGISTER. In such case, the immunity protections provided under section 411(a) of the Act will not apply to the health care entity for professional review activities that occur during the 3-year period beginning 30 days after the date of publication of the entity's name in the FEDERAL REGISTER.

(2) *Board of Medical Examiners.* If, after notice of noncompliance and providing opportunity to correct noncompliance, the Secretary determines that a Board has failed to report information in accordance with paragraph (b) of this section, the Secretary will designate another qualified entity for the reporting of this information.

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Subpart C—Disclosure of Information by the National Practitioner Data Bank

§ 60.10 Information which hospitals must request from the National Practitioner Data Bank.

(a) *When information must be requested.* Each hospital, either directly or through an authorized agent, must request information from the Data Bank concerning a physician, dentist or other health care practitioner as follows:

(1) At the time a physician, dentist or other health care practitioner applies for a position on its medical staff (courtesy or otherwise), or for clinical privileges at the hospital; and

(2) Every 2 years concerning any physician, dentist, or other health care practitioner who is on its medical staff (courtesy or otherwise), or has clinical privileges at the hospital.

(b) *Failure to request information.* Any hospital which does not request the information as required in paragraph (a) of this section is presumed to have knowledge of any information reported to the Data Bank concerning this physician, dentist or other health care practitioner.

(c) *Reliance on the obtained information.* Each hospital may rely upon the information provided by the Data Bank to the hospital. A hospital shall not be held liable for this reliance unless the hospital has knowledge that the information provided was false.

(Approved by the Office of Management and Budget under control number 0915-0126)

§ 60.11 Requesting information from the National Practitioner Data Bank.

(a) *Who may request information and what information may be available.* Information in the Data Bank will be available, upon request, to the persons or entities, or their authorized agents, as described below:

(1) A hospital that requests information concerning a physician, dentist or other health care practitioner who is on its medical staff (courtesy or otherwise) or has clinical privileges at the hospital,

(2) A physician, dentist, or other health care practitioner who requests information concerning himself or herself,

(3) Boards of Medical Examiners or other State licensing boards,

(4) Health care entities which have entered or may be entering employment or affiliation relationships with a physician, dentist or other health care practitioner, or to which the physician, dentist or other health care practioner has applied for clinical privileges or appointment to the medical staff,

(5) An attorney, or individual representing himself or herself, who has filed a medical malpractice action or claim in a State or Federal court or other adjudicative body against a hospital, and who requests information regarding a specific physician, dentist, or other health care practitioner who is also named in the action or claim. Provided, that this information will be disclosed only upon the submission of evidence that the hospital failed to request information from the Data Bank as required by § 60.10(a), and may be used solely with respect to litigation resulting from the action or claim against the hospital.

(6) A health care entity with respect to professional review activity, and

(7) A person or entity who requests information in a form which does not permit the identification of any particular health care entity, physician, dentist, or other health care practitioner.

(b) *Procedures for obtaining National Practitioner Data Bank information.* Persons and entities may obtain information from the Data Bank by submitting a request in such form and manner as the Secretary may prescribe. These requests are subject to fees as described in § 60.12.

[54 FR 42730, Oct. 17, 1989; 54 FR 43890, Oct. 27, 1989]

§ 60.12 Fees applicable to requests for information.

(a) *Policy on Fees.* The fees described in this section apply to all requests for information from the Data Bank, other than those of individuals for information concerning themselves. These fees are authorized by section 427(b)(4) of the Health Care Quality Improvement Act of 1986 (42 U.S.C. 11137). They reflect the costs of processing requests for disclosure and of providing such information. The actual fees will be announced by the Secretary in periodic notices in the FEDERAL REGISTER.

(b) *Criteria for determining the fee.* The amount of each fee will be determined based on the following criteria:

(1) Use of electronic data processing equipment to obtain information—the actual cost for the service, including computer search time, runs, printouts, and time of computer programmers and operators, or other employees,

(2) Photocopying or other forms of reproduction, such as magnetic tapes—actual cost of the operator's time, plus the cost of the machine time and the materials used,

(3) Postage—actual cost, and

(4) Sending information by special methods requested by the applicant, such as express mail or electronic transfer—the actual cost of the special service.

(c) *Assessing and collecting fees.* (1) A request for information from the Data Bank will be regarded as also an agreement to pay the associated fee.

(2) Normally, a bill will be sent along with or following the delivery of the requested information. However, in order to avoid sending numerous small bills to frequent requesters, the charges may be aggregated for certain periods. For example, such a requester may receive a bill monthly or quarterly.

(3) In the event that a requester has failed to pay previous bills, the requester will be required to pay the fee before a request for information is processed.

(4) Fees must be paid by check or money order made payable to "U.S. Department of Health and Human Services" or to the unit stated in the billing and must be sent to the billing unit. Payment must be received within 30 days of the billing date or the applicant will be charged interest and a late fee on the amount overdue.

§ 60.13 Confidentiality of National Practitioner Data Bank information.

(a) *Limitations on disclosure.* Information reported to the Data Bank is considered confidential and shall not be disclosed outside the Department of Health and Human Services, except as specified in § 60.10, § 60.11 and § 60.14. Persons and entities which receive information from the Data Bank either directly or from another party must use it solely with respect to the purpose for which it was provided. Nothing in this paragraph shall prevent the disclosure of information by a party which is authorized under applicable State law to make such disclosure.

(b) *Penalty for violations.* Any person who violates paragraph (a) shall be subject to a civil money penalty of up to $10,000 for each violation. This penalty will be imposed pursuant to procedures at 42 CFR part 1003.

§ 60.14 How to dispute the accuracy of National Practitioner Data Bank information.

(a) *Who may dispute National Practitioner Data Bank information.* Any physician, dentist or other health care practitioner may dispute the accuracy of information in the Data Bank concerning himself or herself. The Secretary will routinely mail a copy of any report filed in the Data Bank to the subject individual.

(b) *Procedures for filing a dispute.* A physician, dentist or other health care practitioner has 60 days from the date on which the Secretary mails the report in question to him or her in which to dispute the accuracy of the report. The procedures for disputing a report are:

(1) Informing the Secretary and the reporting entity, in writing, of the disagreement, and the basis for it,

(2) Requesting simultaneously that the disputed information be entered into a "disputed" status and be reported to inquirers as being in a "disputed" status, and

(3) Attempting to enter into discussion with the reporting entity to resolve the dispute.

(c) *Procedures for revising disputed information.* (1) If the reporting entity revises the information originally submitted to the Data Bank, the Secretary will notify all entities to whom reports have been sent that the original information has been revised.

(2) If the reporting entity does not revise the reported information, the Secretary will, upon request, review the written information submitted by both parties (the physician, dentist or other health care practitioner), and the reporting entity. After review, the Secretary will either—

(i) If the Secretary concludes that the information is accurate, include a brief statement by the physician, dentist or other health care practitioner describing the disagreement concerning the information, and an explanation of the basis for the decision that it is accurate, or

(ii) If the Secretary concludes that the information was incorrect, send corrected information to previous inquirers.

(Approved by the Office of Management and Budget under control number 0915-0126)

[54 FR 42730, Oct. 17, 1989, as amended at 54 FR 43890, Oct. 27, 1989]

PART 63—GRANT PROGRAMS ADMINISTERED BY THE OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION

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AUTHORITY: Sec. 602, Community Services Act (42 U.S.C. 2942); sec. 1110, Social Security Act (42 U.S.C. 1310).

SOURCE: 40 FR 23295, May 29, 1975, unless otherwise noted.

Subpart A—General

§ 63.1 Purpose and scope.

(a) *Applicability.* Except to the extent inconsistent with an applicable Federal statute the regulations in this part apply to all grant awards of Federal assistance made by the Assistant Secretary for Planning and Evaluation or his designee, hereinafter referred to in this part as the Assistant Secretary. Such grants include those under section 232 of the Community Services Act (42 U.S.C. 2835), section 1110 of the Social Security Act (42 U.S.C. 1310), section 392A of the Communications Act of 1934, and such other authority as may be delegated to the Assistant Secretary for policy research activities.

(b) *Exceptions to applicability.* The award and administration of contracts and cooperative agreements by the Assistant Secretary shall not be covered by this subchapter. Contracts entered into by the Assistant Secretary shall be subject to the regulations in 41 CFR Chapters 1 and 3. Generally, the Assistant Secretary will select between grant and contract procedures and instruments, both with regard to the solicitation process and with respect to unsolicited proposals, on the basis of criteria set forth in the proposed revision of 41 CFR 3-1.53 published at 39 FR 27469 at any subsequent revision thereof.

(c) *Objectives*—(1) *Policy Research.* The overall objective of policy research activities is to obtain information, as it relates to the mission of the Department of Health and Human Services, about the basic causes of and methods for preventing and eliminating poverty and dependency and about improved methods for delivering human resources services. Such information is obtained through the conduct of basic and applied research, statistical analyses, and demonstrations and evaluations which have demonstrated a high probability of impacting on the formulation or modification of major Departmental policies and programs.

(2) *Telecommunications Demonstrations.* The overall objective of the Telecommunications Demonstration Program is to promote the development of nonbroadcast telecommunications facilities and services for the transmission, distribution, and delivery of health, education, and social service information.

[40 FR 23295, May 29, 1975, as amended at 42 FR 36149, July 13, 1977]

§ 63.2 Eligibility for award.

(a) *Groups and organizations eligible.* Except where otherwise prohibited by law, any public or nonprofit private agency, institution, or organization which is found by the Assistant Secretary to be authorized and qualified by educational, scientific, or other relevant competence to carry out a proposed project in accordance with the regulations of this subchapter shall be eligible to receive a grant under this part.

(b) *Project eligible*—(1) *Policy Research.* Any project found by the Assistant Secretary to be a research, pilot, evaluation, or demonstration project within the meaning of this section and § 63.1 shall be eligible for an award. Eligible projects may include planning, policy modeling or research utilization studies; experiments; demonstrations; field investigations; statistical data collections or analyses; or other types of investigation or studies, or combinations thereof, and may either be limited to one aspect of a problem or subject, or may consist of two or more related problems or subjects for concurrent or consecutive investigation and may involve multiple disciplines, facilities, and resources.

(2) *Telecommunications Demonstrations.* Any projects which meet the special criteria in § 63.6(c) shall be eligible for a telecommunications demonstration grant.

[40 FR 23295, May 29, 1975, as amended at 42 FR 36149, July 13, 1977]

§ 63.3 Program announcements and solicitations.

(a) In each fiscal year the Assistant Secretary may from time to time solicit applications through one or more general or specialized program announcements. Such announcements will be published in the FEDERAL REGISTER as notices and will include:

(1) A clear statement of the type(s) of applications requested;

(2) A specified plan, time(s) of application, and criteria for reviewing and approving applications;

(3) Any grant terms or conditions of general applicability (other than those set forth in this part) which are necessary (i) to meet the statutory requirements of applicable legislation, (ii) to assure or protect the advancement of the project, or (iii) to conserve grant funds.

(b) Applications for grants: Any applicant eligible for grant assistance may submit on or before such cutoff date or dates as the Assistant Secretary may announce in program solicitations, an application containing such pertinent information and in accordance with the forms and instructions as prescribed herein and additional forms and instructions as may be specified by the Assistant Secretary. Such application shall be executed by the applicant or an official or representative of the applicant duly authorized to make such application. The Assistant Secretary may require any party eligible for assistance under this subchapter to submit a preliminary proposal for review and approval prior to the acceptance of an application submitted under these provisions.

(c) All applications and preliminary proposals should be addressed to:

Grants Officer, Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, 330 Independence Avenue, SW, Room 5027, Washington, DC 20201.

§ 63.4 Cooperative arrangements.

(a) Eligible parties may enter into cooperative arrangements with other eligible parties, including those in another State, to apply for assistance.

(b) A joint application made by two or more applicants for assistance under this subchapter may have separate budgets corresponding to the programs, services and activities performed by each of the joint applicants or may have a combined budget. If joint applications present separate budgets, the Assistant Secretary may make separate awards, or may award a single grant authorizing separate amounts for each of the joint applicants.

(c) In the case of each cooperative arrangement authorized under paragraph (a) of this section and receiving assistance, except where the Assistant Secretary makes separate awards under paragraph (b) of this section all such applicants (1) shall be deemed to be joint legal recipients of the grant award and (2) shall be jointly and severally responsible for administering the project assisted under such grant.

§ 63.5 Effective date of approved grant.

Federal financial participation is normally available only with respect to obligations incurred subsequent to the effective date of an approved project. The effective date of the project will be set forth in the notification of grant award. Grantees may be reimbursed for costs resulting from obligations incurred before the effective date of the grant award if such costs are authorized by the Assistant Secretary in the notification of grant award or subsequently in writing, and otherwise would be allowable as costs of the grant under the applicable regulations and grant terms and conditions.

§ 63.6 Evaluation of applications.

(a) *Review procedures.* All applications filed in accordance with § 63.3 shall be evaluated by the Assistant Secretary through officers, employees, and such experts or consultants engaged for this purpose as he/she determines are specially qualified in the areas of research pursued by this office. The evaluation criteria below will be supplemented each fiscal year by a program announcement outlining priorities and objectives for policy research, and by other general or specialized solicitations. Such supplements may modify the criteria in paragraphs (b) and (c) of this section to provide greater specificity or otherwise improve their applicability to a given announcement or solicitation.

(b) *Criteria for evaluation of Policy Research Projects.* Review of applications under paragraph (a) of this section will take into account such factors as:

(1) Scientific merit and the significance of the project in relation to policy objectives;

(2) Feasibility of the project;

(3) Soundness of research design, statistical technique, and procedures and methodology;

(4) Theoretical and technical soundness of the proposed plan of operation including consideration of the extent to which:

(i) The objectives of the proposed project are sharply defined, clearly stated, and capable of being attained by the proposed procedures;

(ii) The objectives of the proposed project show evidence of contributing to the achievement of policy objectives;

(iii) Provisions are made for adequate evaluation of the effectiveness of the project and for determining the extent to which the objectives are accomplished; and

(iv) Appropriate provisions are made for satisfactory inservice training connected with project services.

(5) Expected potential for utilizing the results of the proposed project in other projects or programs for similar purposes;

(6) Sufficiency of size, scope, and duration of the project so as to secure productive results;

(7) Adequacy of qualifications and experience, including managerial, of personnel;

(8) Adequacy of facilities and other resources; and

(9) Reasonableness of estimated cost in relation to anticipated results.

(c) *Criteria for evaluation of Telecommunications Demonstrations Projects.* Review of applications for Telecommunications Demonstrations grants will take into account such factors as are listed in paragraphs (c) (1) through (10) of this section. Each applicant must include in the application, prior to final evaluation by the Assistant Secretary, documentation indicating specifically and separately how and to what extent each of these criteria have been or will be met:

(1) That the project for which application is made demonstrates innovative methods or techniques of utilizing nonbroadcast telecommunications equipment or facilities to satisfy the purpose of this authority;

(2) That the project will have original research value which will demonstrate to other potential users that such methods or techniques are feasible and cost-effective;

(3) That the services to be provided are responsive to local needs as identified and assessed by the applicant;

(4) That the applicant has assessed existing telecommunications facilities (if any) in the proposed service area and explored their use of interconnection in conjunction with the project;

(5) That there is significant local commitment (e.g., evidence of support, participation, and contribution by local institutions and agencies) to the proposed project, indicating that it fulfills local needs, and gives some promise that operational systems will result from successful demonstrations and will be supported by service recipients or providers;

(6) That demonstrations and related activities assisted under this section will remain under the administration and control of the applicant;

(7) That the applicant has the managerial and technical capability to carry out the project for which the application is made;

(8) That the facilities and equipment acquired or developed pursuant to the applications will be used substantially for the transmission, distribution, and delivery of health, education, or social service information, and that use of such facilities and equipment may be shared among these and additional public or other services;

(9) That the provision has been made to submit a summary and factual evaluation of the results of the demonstration at least annually for each year in which funds are received, in the form of a report suitable for dissemination to groups representative of national health, education, and social service telecommunications interests; and,

(10) That the project has potential for stimulating cooperation and sharing among institutions and agencies, both within and across disciplines.

(d) *Applicant's performance on prior award.* Where the applicant has previously received an award from the Department of Health and Human Services, the applicant's compliance or noncompliance with requirements applicable to such prior award as reflected in past written evaluation reports, memoranda on performance, and completeness of required submissions: *Provided,* That in any case where the Assistant Secretary proposes to deny assistance based upon the applicant's noncompliance with requirements applicable to a prior award, he shall do so only after affording the applicant reasonable notice and an opportunity to rebut the proposed basis for denial of assistance.

[40 FR 23295, May 29, 1975, as amended at 42 FR 36149, July 13, 1977]

§ 63.7 Disposition of applications.

(a) *Approval, disapproval, or deferral.* On the basis of the review of an application pursuant to § 63.6 the Assistant Secretary will either (1) approve the application in whole or in part, for such amount of funds and subject to such conditions as he/she deems necessary or desirable for the completion of the approved project, (2) disapprove the application, or (3) defer action on the application for such reasons as lack of funds or a need for further review.

(b) *Notification of disposition.* The Assistant Secretary will notify the applicant in writing of the disposition of its application. A signed notification of grant award will be issued to notify the applicant of an approved project application.

§ 63.8 Supplemental regulations and grant conditions.

(a) *Grants under section 232 of the Community Services Act.* (1) Any grants awarded with funds appropriated under section 232 of the Community Services Act shall be subject to the following regulations issued by the Director of the Community Services Administration (formerly the Office of Economic Opportunity):

45 CFR 1060.2	(Income Poverty Guidelines.)
45 CFR 1060.3	(Limitation on Benefits to Those Voluntarily Poor.)
45 CFR 1067.1	(Suspension and Termination of Assistance.)
45 CFR 1068.6	(Grantee Compliance with IRS Requirements for Withheld Federal Income and Social Security Taxes.)
45 CFR 1069.1	(Employee Participation in Direct Action.)
45 CFR 1069.2	(Limitations with Respect to Unlawful Demonstrations, Rioting, and Civil Disturbances.)
45 CFR 1070.1	(Public Access to Grantee Information.)

No other portions of Chapter X of this title are applicable to such grants.

(2) Grants awarded with funds appropriated under section 232 of the Community Services Act shall also be subject to the applicable statutory requirements in sections 242, 243, and 244, and title VI of the Community Services Act. The Assistant Secretary will advise grantees of the nature of these requirements at or prior to the time of award.

(3) In the event that any provision of this part is inconsistent with a provision of law or a regulation referenced in paragraphs (a)(1) and (2) of this section with respect to any grant funded under section 232 of the Community Services Act, the provision of this part shall, to the extent of any such inconsistency, not be effective.

(b) *Grants under other statutory authority.* Grants awarded by the Assistant Secretary may be subject to regulations, other than those set forth in this part, which have been issued under the authority of statutes authorizing particular awards. In such a case, that fact will be set forth in the program announcement soliciting applications for such grants published in the FEDERAL REGISTER pursuant to § 63.3.

(c) *Other regulations applicable to grants under this part.* Federal financial assistance provided under this part shall be subject to the following additional regulations except as otherwise provided in this part:

(1) Part 74 of this title, establishing uniform administrative requirements and cost principles for grants by the Department of Health and Human Services.

(2) Part 80 of this title, effectuating the provisions of title VI of the Civil Rights Act of 1964; and

(3) Part 16 of this title, establishing a Departmental Grant Appeals Board for the resolution of specified post-award grant disputes.

Subpart B—Financial Provisions

§ 63.16 Scope of subpart.

This subpart sets forth supplemental financial provisions which apply to all grants awarded by the Assistant Secretary, except as specified in § 63.23 of this subpart.

[40 FR 23295, May 29, 1975, as amended at 42 FR 36149, July 13, 1977]

§ 63.17 Amount of award.

Federal assistance shall be provided only to meet allowable costs incurred by the award recipient in carrying out an approved project in accordance with the authorizing legislation and the regulations of this part.

§ 63.18 Limitations on costs.

The amount of the award shall be set forth in the grant award document. The total cost to the Government will not exceed the amount set forth in the grant award document or any modification thereof approved by the Assistant Secretary which meets the requirements of applicable statutes and regulations. The Government shall not be obligated to reimburse the grantee for costs incurred in excess of such amount unless and until the Assistant Secretary has notified the grantee in writing that such amount has been increased and has specified such increased amount in a revised grant award document. Such revised amount shall thereupon constitute the maximum cost to the Government for the performance of the grant.

§ 63.19 Budget revisions and minor deviations.

Pursuant to § 74.102(d) of this title, paragraphs (b)(3) and (b)(4) of that section are waived.

§ 63.20 Period during which grant funds may be obligated.

(a) The amount of the grant award shall remain available for obligation by the grantee during the period specified in the grant award or until otherwise terminated. Such period may be extended by revision of the grant with or without additional funds pursuant to paragraph (b) of this section where otherwise permitted by law.

(b) When it is determined that special or unusual circumstances will delay the completion of the project beyond the period for obligation, the grantee must in writing request the Assistant Secretary to extend such period and must indicate the reasons therefor.

§ 63.21 Obligation and liquidation by grantee.

Obligations will be considered to have been incurred by a grantee on the basis of documentary evidence of binding commitments for the acquisition of goods or property or for the performance of work, except that funds for personal services, for services performed by public utilities, for travel, and for the rental of facilities, shall be considered to have been obligated as of the time such services were rendered, such travel was performed, and such rented facilities were used, respectively.

§ 63.22 Cost sharing.

Policy Research funds shall not be used to pay any recipient of a grant for the conduct of a research project an amount equal to as much as the entire cost of the project.

§ 63.23 Telecommunications Demonstration Grants.

The provisions of this section apply only to grants awarded under authority of 392A of the Communications Act of 1934.

(a) Funds provided under the Telecommunications Demonstrations Program shall be available to support the planning, development, and acquisition or leasing of facilities and equipment necessary to the demonstration. However, funds shall not be available for the construction, remodeling, or repair of structures to house facilities or equipment acquired or developed with such funds, except that such funds may be used for minor remodeling which is necessary for and incident to the installation of such facilities or equipment.

(b) Funds shall not be available for the development of programming materials or content.

(c) The funding of any demonstration under this authority shall continue for not more than three years from the date of the original grant or contract.

(1) Applications for assistance under the Act may project goals and activities over a period of up to three years. Approval of a multi-year project is intended to offer the project a reasonable degree of stability over time and to facilitiate additional long range planning.

(2) Applications proposing a multi-year project must be accompanied by an explanation of the need for multi-year support, an overview of the objectives and activities proposed, and budget estimates to attain these objectives in any proposed subsequent year.

(3) Subject ,to the availability of funds, an application for assistance to continue a project during the project period will be reviewed on a non-competitive basis to determine—

(i) If the award recipient has complied with the award terms and conditions, the Act, and applicable regulations;

(ii) The effectiveness of the project to date in terms of progress toward its goals, or the constructive changes proposed as a result of the ongoing evaluation of the project; and,

(iii) If continuation of the project would be in the best interests of the Government.

(d) The use of equipment in demonstration projects shall be subject to the rules and regulations of the Federal Communications Commission (FCC), and grant funds may not be expended or obligated for purchase, lease, or use of such equipment prior to appropriate and necessary coordination by the grantee with the Commission. In particular:

(1) For any project requiring a new or modification of an existing authorization(s) from the FCC, application(s) to the FCC for such authorization(s) must have been tendered for filing prior to the closing date established by any solicitation for grant applications offered under the Telecommunications Demonstration Program.

(2) If the project is to be associated with an existing telecommunications activity requiring an FCC authorization, such operating authority for that activity must be current and valid.

(3) For any project requiring a new or modification of an existing authorization(s) from the FCC, the applicant must file with the Secretary of Health and Human Services a copy of each FCC application and any amendments thereto.

(4) For any project requiring a new or modification of an existing authorization(s) from the FCC, the applicant must tender for filing with the FCC a copy of the application to the Secretary for a telecommunications demonstration grant.

(5) If the applicant fails to file required applications by the closing date established by the solicitation for grant applications, or if the FCC returns as substantially incomplete or deficient, dismisses, or denies an application required for the project, or any part thereof, or for the operation of any facility with which the project is associated, the Secretary may return the application for Federal assistance.

(e) For the purposes of this program, the term "non-broadcast telecommunications facilities" includes but is not limited to, cable television systems, communications satellite systems and related terminal equipment, and other methods of transmitting, emitting, or receiving images and sounds or intelligence by means of wire, radio, optical, electromagnetic, and other means (including non-broadcast utilization of telecommunications equipment normally associated with broadcasting use).

(f) Each applicant shall provide such information as the Assistant Secretary deems necessary to make a Federal assessment of the impact of the project on the quality of the human environment in accordance with section 102(2)(C) of the National Environmental Policy Act of 1969 (including the National Historical Preservation Act and other environmental acts). (42 U.S.C. 4332(2)(C)).

[42 FR 36149, July 13, 1977]

Subpart C—Special Provisions

§ 63.30 Scope of subpart.

This subpart sets forth supplemental special provisions which apply to all grants awarded by the Assistant Secretary.

§ 63.31 Protection of human subjects.

All grants made pursuant to this part are subject to the specific provisions of Part 46 of this subtitle relating to the protection of human subjects.

§ 63.32 Data collection instruments.

(a) *Definitions.* For the purposes of this section "Child" means an individual who has not attained the legal age of consent to participate in research as determined under the applicable law of the jurisdiction in which such research is to be conducted.

"Data-collection instruments" means tests, questionnaires, inventories, interview schedules or guides, rating scales, and survey plans or any other forms which are used to collect information on substantially identical items from 10 or more respondents.

"Respondents" means individuals or organizations from whom information is collected.

(b) *Applicability.* This section does not apply to instruments which deal solely with (1) functions of technical proficiency, such as scholastic aptitude or school achievement, or (2) routine demographic information.

(c) *Protection of privacy.* (1) No project supported under this part may involve the use of data collection instruments which constitute invasion of personal privacy through inquiries regarding such matters as religion, sex, race, or politics.

(2) A grantee which proposes to use a data collection instrument shall set forth in the grant application an explanation of the safeguards which will be used to restrict the use and disclosure of information so obtained to purposes directly connected with the project, including provisions for the destruction of such instruments where no longer needed for the purposes of the project.

(d) *Clearance of instruments.* (1) Grantees will not be required to submit data-collection instruments to the Assistant Secretary or obtain the Assistant Secretary's approval for the use of these instruments, except where the notification of grant award specifically so provides.

(2) If a grantee is required under paragraph (d)(1) of this section to submit data-collection instruments for the approval of the Assistant Secretary or if a grantee wishes the Assistant Secretary to review a data-collection instrument, the grantee shall submit seven copies of the document to the Assistant Secretary along with seven copies of the Office of Management and Budget's standard form No. 83 and seven copies of the Supporting Statement as required in the "Instructions for Requesting OMB Approval under the Federal Reports Act" (Standard form No. 83A).

(e) *Responsibility for collection of information.* A grantee shall not in any way represent or imply (either in a letter of transmittal, in the data-gathering instruments themselves, or in any other manner) that the information is being collected by or for the Federal Government or any department, agency or instrumentality thereof. Basic responsibility for the study and the data-gathering instruments rests with the grantee.

(f) *Parental consent.* In the case of any survey using data-collection instruments in which children are involved as respondents, the grantee, in addition to observing the other requirements contained in this section, and in Part 46 of this subtitle as appropriate, shall provide assurances satisfactory to the Assistant Secretary that informed consent will be obtained from the parents of each such respondent prior to the use of such instruments, except that a waiver from the requirements of this paragraph for specific data-collection activities may be granted upon the written request by the grantee and a determination by the Assistant Secretary that a waiver is necessary in order to fully carry out the purposes of the grant.

§ 63.33 Treatment of animals.

If animals are utilized in any project receiving assistance, the applicant for such assistance shall provide assurances satisfactory to the Assistant Secretary that such animals will be provided with proper care and humane treatment; in accordance with the Animal Welfare Act (7 U.S.C. 2131 et seq.) and regulations set forth in (9 CFR Parts 1, 2, 3, 4).

§ 63.34 Principal investigators.

The principal investigator(s) designated in successful grant applications as responsible for the conduct of the approved project, shall not be replaced without the prior approval of the Assistant Secretary or his designee. Failure to seek and acquire such approval may result in the grant award being terminated in accordance with the procedures set forth in § 74.114 of this subtitle or such other regulations as may be indicated in the grant terms and conditions.

§ 63.35 Dual compensation.

If a project staff member or consultant of one grantee is involved simultaneously in two or more projects supported by any funds either under this part or otherwise, he/she may not be compensated for more than 100 percent of his/her time from any funds during any part of the period of dual involvement.

§ 63.36 Fees to Federal employees.

The grantee shall not use funds from any sources to pay a fee to, or travel expenses of, employees of the Federal Government for lectures, attending program functions, or any other activities in connection with the grant.

§ 63.37 Leasing facilities.

In the case of a project involving the leasing of a facility, the grantee shall demonstrate that it will have the right to occupy, to operate, and, if necessary, to maintain and improve the leased facility during the proposed period of the project.

§ 63.38 Publications.

Any publication or presentation resulting from or primarily related to Federal financial assistance under this part shall contain an acknowledgement essentially as follows:

> The activity which is the subject of this report was supported in whole or part by a grant from the Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services. However, the opinions expressed herein do not necessarily reflect the position or policy of that Office and no official endorsement by that Office should be inferred.

§ 63.39 Religious worship or instruction.

Federal funds shall not be used for the making of any payment for religious worship or instruction, or for the construction, operation, or maintenance of so much of any facility as is used or to be used for sectarian instruction or as a place for religious instruction.

PART 73—STANDARDS OF CONDUCT

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APPENDIX B TO PART 73—CODE OF ETHICS FOR GOVERNMENT SERVICE

AUTHORITY: 5 U.S.C. 7301, 42 U.S.C. 216; E.O. 11222, 30 FR 6469; 5 CFR 735.101 *et seq.*

SOURCE: 46 FR 7369, Jan. 23, 1981, unless otherwise noted.

Subpart A—General Provisions

§ 73.735-101 Purpose.

To assure that the business of the Department of Health and Human Services (HHS) is conducted effectively, objectively, and without improper influence or the appearance of improper influence, employees and special Government employees must be persons of integrity and must observe high standards of honesty, impartiality, and behavior. They must not engage in any conduct prejudicial to the Government and must avoid conflicts of private interests with public duties and responsibilities. In accord with these principles, the regulations in this part are issued to inform HHS employees and special Government employees what standards of conduct are expected of them in performing their duties and what activities are permitted or prohibited both while they are employed and after their employment with the Department is ended.

§ 73.735-102 Definitions.

In this part:

(a) "Employee" means an officer or employee of HHS other than a special Government employee and includes Commissioned Officers of the Public Health Service who are on active duty, and individuals on assignment or detail to HHS pursuant to the Intergovernmental Personnel Act (5 U.S.C. 3371-3376). The term also includes HHS employees who are detailed to non-Federal or other Federal organizations. At times the term "regular employee" is used in place of "employee" to make a clear distinction between special Government employees and others employed by the Federal government.

(b) "Special Government employee" means an individual who is retained, designated, appointed, or employed to perform temporary duties either on a full-time or intermittent basis, with or without compensation, for not to exceed 130 days during any period of 365 consecutive days.

(c) "Person" means an individual, a corporation, a company, an association, a firm, a partnership or any other organization.

(d) "Former employee" means a former employee of HHS or former special Government employee as defined in paragraph (b) of this section.

(e) "Principal Operating Component" has the meaning given to that term in the Department's General Administration Manual. In addition, when used in these regulations, it includes the Office of the Secretary.

(f) "Department" means the Department of Health and Human Services.

§ 73.735–103 Applicability.

(a) The regulations in this part apply to all employees of the Department and to special Government employees to the extent indicated in Subparts J and K. They apply whether an employee is on leave, including leave without pay, or on duty.

(b) These regulations may be supplemented by regulations governing principal operating components, or subunits of principal operating components, provided the clearance and publication requirements for standards of conduct regulations are met and approval is obtained from the Department Ethics Counselor and the Assistant Secretary for Personnel Administration.

Subpart B—Responsibilities

§ 73.735–201 Employees and supervisors.

(a) Employees and special Government employees shall be responsible for observing all generally accepted rules of conduct and the specific provisions of law and the regulations of this part that apply to them. They are required to become familiar with these regulations and to exercise informed judgments to avoid misconduct or conflicts of interest. They shall secure approvals when required and file financial disclosure reports or statements in accordance with the provisions of this part. Failure to observe any of these regulations may be cause for disciplinary action. Some of the provisions are required by law and carry criminal penalties which are in addition to any disciplinary action which could be taken. When employees have doubts about any provision, they should consult their supervisor, personnel office, or the Department Ethics Counselor or a deputy counselor.

(b) Supervisors, because of their day-to-day relationships with employees, are responsible to a large degree for making sure high standards of conduct are maintained. They must become familiar with the Department's standards of conduct regulations and apply the standards to the work they do and supervise. Supervisors shall take suitable action, including disciplinary action in accordance with Subpart L of these regulations, when violations occur.

§ 73.735–202 Management officials.

(a) The Department has an obligation to enforce the requirements of this part in all respects and to help employees, special Government employees, and supervisors carry out their responsibilities to maintain high standards of ethical conduct. This includes an obligation for managers to provide information and training concerning the HHS conduct regulations, to provide advice and guidance with respect to them, and to review for possible conflicts of interest certain outside activities and financial interests of employees. The officials responsible for discharging the Department's obligations in this regard are identified in paragraphs (b) through (f) of this section.

(b) Department Ethics Counselor. The Assistant General Counsel, Business and Administrative Law Division, shall be the Department Ethics Counselor and shall serve as the Designated Agency Official for matters arising under the Ethics in Government Act of 1978, (Pub. L. 95–521). The responsibilities of the Department Ethics Counselor shall include:

(1) Rendering authoritative advice and guidance on matters of general applicability under the standards of this part and all other laws and regulations governing employee conduct, with particular reference to conflicts of interest matters.

(2) Coordinating the Department's counselling and training services regarding conflicts of interest and assuring that employees of the Department are kept informed of developments in conflict of interest laws and other related matters of ethics.

(3) Receiving information on conflicts of interest and appearances of conflicts of interest involving employees of the Department and forwarding this information to the appropriate management official, or the Inspector General, as necessary, with his or her legal evaluation of the matters addressed.

(4) Reviewing the financial disclosure reports, requests for approval of outside activities, and similar reports filed by Executive level officers, noncareer executives, deputy ethics counselors, and Schedule C employees in the Office of the Secretary for the purpose of identifying and resolving possible and actual conflicts of interest.

(5) Maintaining liaison with the Office of Government Ethics.

(6) Advising management officials on the resolution of conflicts of interest by any of the remedies set forth in § 73.735-904 of this part.

(7) Maintaining accurate and complete documentation of all formal guidance and advice regarding conflict of interest matters subject to the provisions of this part, except for routine or repetitious cases where the guidance given is not precedential.

(8) Maintaining and publishing from time to time a list of those circumstances or situations which have resulted or may result in noncompliance with conflict of interest laws or regulations. [Section 206(b)(7), Pub. L. 95-521].

(9) Designating and training an appropriate number of reviewing officials to assist him or her in carrying out the duties of the Designated Agency Offical under the Ethics in Government Act.

(10) Maintaining effective lines of communication with deputy ethics counselors on all matters regarding employee conduct and ethics.

(c) Deputy Ethics Counselors. Assistant General Counsels and Regional Attorneys are designated deputy ethics counselors to assist the Department's Counselor in carrying out his or her responsibilities, particularly with respect to employees in the organization in which the deputy counselor serves. Regional Attorneys shall provide such assistance for all employees of the Department in organizations for which the Principal Regional Official provides personnel services.

(d) The Assistant Secretary for Personnel Administration shall be responsible for developing and issuing procedures and requirements for the implementation of these regulations and for monitoring the application of such procedures and requirements throughout the Department.

(e) Heads of Principal Operating Components and the Assistant Secretary for Management and Budget for the Office of the Secretary shall be ultimately responsible for assuring that persons who work for their respective organizations comply with the standards of this part. Their responsibilities shall include:

(1) Designating officials to review and approve outside activity requests in accordance with § 73.735-708 of this part or statements of employment or financial interests under § 73.735-902. A list of the officials designated for these purposes shall be provided to the Department Ethics Counselor and to the Assistant Secretary for Personnel Administration and shall be updated in January and July of each year.

(2) Designating for the components of his or her organization, other than those for which a principal regional official provides personnel services, one or more individuals to oversee and coordinate the administrative aspects of these regulations. Responsibilities of such a person include making sure each employee or special government employee is provided a copy of these regulations, or an appropriate summary thereof; ensuring that training in the requirements of the regulations is provided to supervisors and to new em-

ployees; providing for the distribution, receipt, review and retention of financial interest reports and statements as directed by the Department Ethics Counselor and the Assistant Secretary for Personnel Administration; sending annual reminders as required; providing for a file of outside work requests; giving information and assistance to employees on a day-to-day basis; and making available to employees the names and addresses of the Department's Ethics Counselor and deputy ethics counselors.

(f) Principal Regional Officials (PROs) shall designate one or more regional employees to perform, for components for which personnel services are provided by the PROs, the responsibilities in paragraph (e)(2) of this section.

Subpart C—Conduct on the Job

§ 73.735-301 Courtesy and consideration for others.

(a) An employee's conduct on the job is, in all respects, of concern to the Federal government. Courtesy, consideration, and promptness in dealing with the public must be shown in carrying out official responsibilities, and actions which deny the dignity of individuals or conduct which is disrespectful to others must be avoided. Employees must recognize that inattention to matters of common courtesy can adversely affect the quality of service the Department is responsible for providing. Where appropriate, courtesy to the public should be included in the standards for employee performance.

(b) Of equal importance is the requirement that courtesy be shown in day-by-day interaction with co-workers. Employees shall be polite to and considerate of other employees, and shall respect their needs and concerns in the work environment.

§ 73.735-302 Support of department programs.

(a) When a Department program is based on law, Executive Order or regulation, every employee has a positive obligation to make it function as efficiently and economically as possible and to support it as long as it is a part of recognized public policy. An employee may, therefore, properly make an address explaining and interpreting such a program, citing its achievements, defending it against uninformed or unjust criticism, or soliciting views for improving it.

(b) An employee shall not, either directly or indirectly, use appropriated funds to influence, or attempt to influence, a Member of Congress to favor or oppose legislation. However, when authorized by his or her supervisor, an employee is not prohibited from:

(1) Testifying, on request, as a representative of the Department on pending legislation or proposals before Congressional Committees; or

(2) Assisting Congressional Committees in drafting bills or reports on request, when it is clear that the employee is serving solely as a technical expert under the direction of committee leadership.

(c) All employees shall be familiar with regulations and published instructions that relate to their official duties and responsibilities and shall comply with those directives. This includes carrying out proper orders from officials authorized to give them.

(d) Employees are required to assist the Inspector General and other investigative officials in the performance of their duties or functions. This requirement includes the giving of statements or evidence to investigators of the Inspector General's office or other HHS investigators authorized to conduct investigations into potential violations.

§ 73.735-303 Use of government funds.

(a) An employee shall not:

(1) Improperly use official travel;

(2) Improperly use payroll and other vouchers and documents on which Government payments are based;

(3) Take or fail to account for funds with which the employee is entrusted in his or her official position; or

(4) Take other Government funds for personal use. Violation of these prohibitions carry criminal penalties.

(b) In addition, employees shall avoid wasteful actions or behavior in the performance of their assigned duties.

§ 73.735–304 Use of Government property.

(a) An employee shall not directly or indirectly use, or allow the use of, Government property of any kind, including property leased to the Government, for other than officially approved activities. An Employee has a positive duty to protect and conserve Government property, including equipment, supplies, and other property entrusted or issued to him or her. For example:

(1) Only official documents and materials may be processed on Government reproduction facilities. Both supervisors and employees must assure that this rule is strictly followed. (Exception for employee welfare and recreation associations is stated in Chapter 25–10, General Administration Manual. Exception for labor organizations is stated in Personnel Instruction 711–1.)

(2) Employees may drive or use Government automobiles or aircraft only on official business. Use of a Government owned, leased, or rented vehicle or aircraft for non-official purposes may result in suspension for at least 30 days or removal from the Federal service. 31 U.S.C. 638a.

Example: Normally, use of a Government automobile by travel between home and place of duty would not be considered official business and could not be authorized. An exception to this rule might be appropriate in a situation where an employee is required to leave early in the morning to attend a meeting in a distant city, or to return late in the day from such a meeting. Allowing the employee to drive a government car to his or her home the night before in order to leave from home, or to return to his or her home in the evening upon completion of the trip is permissible, provided the employee does not use the car for any personal reason.

§ 73.735–305 Conduct in Federal buildings.

(a) An employee shall not participate while on Government-owned or leased property or while on duty for the Government, in any gambling activity including the operation of a gambling device, in conducting a lottery or pool, in a game for money or property, or in selling or purchasing a numbers slip or ticket.

(b) An employee shall not while in or on Government-owned or leased property or while on duty for the Government solicit alms and contributions, engage in commercial soliciting and vending, display or distribute commercial advertisements, or collect private debts.

(c) The prohibitions in paragraphs (a) and (b) of this section do not preclude:

(1) Activities necessitated by an employee's law enforcement duties;

(2) Participation in Federally sponsored fund-raising activities conducted pursuant to Executive Order 10927, or similar HHS-approved activities; or

(3) Buying a lottery ticket at an authorized State lottery outlet for a lottery authorized by State law and conducted by an agency of a State within that State.

(d) General Services Administration regulations on "Conduct on Federal Property" apply to all property under the control of the General Services Administration, and they are also applicable to all buildings and space under the control of this Department. These regulations prohibit, among other things, gambling, being intoxicated, and possession, distribution, or use of narcotic or dangerous drugs on the premises. The GSA regulations are found in Subpart 101–20.3 of the GSA Regulations, 41 CFR 101–20.3.

§ 73.735–306 Sexual harassment.

Sexual harassment is deliberate unsolicited verbal comments, gestures, or physical contact of a sexual nature which are unwelcome. Sexual harassment is unacceptable conduct and is expressly prohibited. In addition, supervisors and managers are prohibited from taking or promising personnel actions in exchange for sexual favors, or failing to take an action because an employee or applicant for employment, refuses to engage in sexual conduct. This same prohibition applies to relationships between Department personnel who take or recommend action on a grant or contract and the grantee or contractor. Those employees who wish to file a complaint of sexual harassment should contact the Office of Equal Employment Opportunity (EEO) within their respective agencies for guidance. (Time frames for pursuing a charge alleging sexual harassment are the same as for any other complaint based on allegations of sex discrimination.)

§ 73.735-307 Use of official information.

(a) The public interest requires that certain information in the possession of the Government be kept confidential, and released only with general or specific authority under Department or operating component regulations. Such information may involve the national security or be private, personal, or business information which has been furnished to the Government in confidence. In addition, information in the possession of the Government and not generally available may not be used for private gain. The following paragraphs set forth the rules to be followed by Department employees in handling information in official files or documents:

(1) *Classified information.* Employees who have access to information which is classified for security reasons in accordance with Executive Order 12065 are responsible for its custody and safekeeping, and for assuring that it is not disclosed to unauthorized persons. See the Department's Security Manual, Part 3 for details.

(2) *Security and investigative information.* Security and investigative data received from Government agencies or other sources for official use only within the Department or developed under a pledge of confidence is not to be divulged to unauthorized persons or agencies.

(3) *Information obtained in confidence.* Certain Department units (e.g., Food and Drug Administration, and the Social Security Administration) obtain in the course of their program activities certain information from businesses or individuals which they are forbidden by law from disclosing. These statutory prohibitions are found in 21 U.S.C. 331j, and 18 U.S.C. 1905. Each employee is responsible for observing these laws.

(4) *Use of information for private gain.* Government employees are sometimes able to obtain information about some action the Government is about to take or some other matter which is not generally known. Information of this kind shall not be used by the employee to further his or her or someone else's private financial or other interests. Such a use of official information is clearly a violation of a public trust. Employees shall not, directly or indirectly, make use of, or permit others to make use of, for the purpose of furthering any private interest, official information not made available to the general public.

(b) The Privacy Act provides criminal penalties for an employee who willfully discloses individually identifiable information from records, disclosure of which is prohibited by that Act. 5 U.S.C. 552a(i).

Subpart D—Financial Obligations

§ 73.735-401 General provisions.

(a) The Department considers the indebtedness of its employees to be a matter of their own concern. However, employees shall not by failure to meet their just financial obligations reflect adversely on the Government as their employer. Employees are expected to pay each just financial obligation in a proper and timely manner. A "just financial obligation" is one acknowledged by the employee or reduced to judgment by a court, or one imposed by law such as Federal, State, or local taxes. "In a proper and timely manner" is a manner which the Department determines does not, under the circumstances, reflect adversely on the part of an employee in meeting his or her financial obligations, particularly those that relate to support of the employee's family, to payment of Federal, State, or local taxes, or to payments to tax-supported institutions such as a city or state hospital, or educational institution. If for some reason an employee is unable to pay these obligations promptly, he or she is expected to make satisfactory arrangements for payment and abide by these arrangements.

(b) Disciplinary action may be considered when an employee has handled his or her financial affairs in such a way that:

(1) Action on complaints received from creditors requires the use of a

considerable amount of official time, or

(2) It appears that financial difficulties are impairing the employee's efficiency on the job, or

(3) Because of the employee's financial irresponsibility, the attitude of the general public toward the Department may be adversely affected; and the employee after counseling does not make arrangements to meet his or her financial obligations.

Subpart E—Gifts, Entertainment, and Favors

§ 73.735–501 Prohibited acceptance of gifts, entertainment, and favors.

(a) Except as provided in §§ 73.735–502 and 73.735–506, an employee shall not directly or indirectly solicit or accept anything of monetary value, including gifts, gratuities, favors, entertainment or loans from a person who the employee knows, or should know because of the nature of the employee's work:

(1) Has, or is seeking to obtain, contractual or other business or financial relations with the employee's principal operating component, or sub-unit thereof; or with a component of the Department with respect to which the employee has official duties;

(2) Conducts operations or activities that are regulated by the employee's principal operating component, or sub-unit thereof or by a component of the Department with respect to which the employee has official duties; or

(3) Has interests that may be substantially affected by the performance or non-performance of the employee's official duties.

(b) Employees may not designate a person or an organization, including charitable or non-profit organizations, to accept any gift which an employee is prohibited from accepting directly.

§ 73.735–502 Permissible acceptance of gifts, entertainment and favors.

(a) An employee may accept a gift, gratuity, favor, entertainment, loan or similar favor of monetary value which stems from a family relationship such as that between the employee and his or her parents, spouse or children, if it is clear that the relationship is the motivating factor.

(b) Loans from banks or other financial institutions may be accepted on customary terms.

(c) Unsolicited advertising or promotional material such as pens, note pads, calendars and similar items of nominal intrinsic value may be accepted.

(d) An employee may accept food or refreshment of nominal value on infrequent occasions in the ordinary course of a luncheon or dinner meeting or on an inspection tour only if the employee is properly in attendance and there is not a reasonable opportunity to pay.

Example 1: Employee is on the premises of Company participating in a meeting at a normal mealtime. A representative of Company provides a meal for all meeting participants from a Company facility and there is no established method for payment. Employee may accept.

Example 2: Employee is on the premises of Company and he or she goes outside for lunch with a representative of the Company. The representative offers to pay the bill. Since it is practical for the employee to pay for his or her own meal, the employee may not accept.

(e) An employee may also accept food or refreshment of nominal value on infrequent occasions if the food and/or refreshment is offered to all participants or attendees of a meeting or convention.

Example 1: During the course of a convention of a professional organization a luncheon open to all attendees is sponsored by a corporation which conducts business with the Department and the employee has official dealings with representatives of the corporation. The employee may attend the luncheon.

§ 73.735–503 Criminal provisions relating to gifts, entertainment, and favors.

(a) The law provides criminal penalties for whoever, directly or indirectly:

(1) Receives or accepts anything of value for or because of any official act the employee has performed or will perform; or

(2) Gives, offers or promises anything of value for the performance of an official act or to influence the per-

formance of an official act. 18 USC 201.

(b) The law prohibits an employee from receiving any salary or any contribution to, or supplementation of, his or her salary as compensation for services as an officer or employee of the Government from any source other than the United States or any state, county or municipality. This law does not prohibit an employee from continuing to participate in a bona fide pension, retirement, group life, health or accident insurance, profit-sharing, stock bonus or other employee welfare or benefit plan maintained by a former employer. 18 U.S.C. 209.

Example 1: A corporate executive is asked to accept a position in the Department. The corporation offers to continue to pay the executive the difference between his or her salary as a Government employee and that received by an employee of the corporation. Such payment would be considered to be "compensation for" the employee's Government service and is prohibited.

Example 2: A corporate executive is asked to accept a position in the Department. The corporation proposes to pay him or her a special severance payment in anticipation of this or her serving in the Government. This proposal would be prohibited because there is no distinction between the proposed lump-sum payment and the prohibited continuation of salary payments described in the example above.

Example 3: A corporate executive is asked to accept a position in the Department. The corporation has an established policy which provides for an amount of severance pay to be paid any departing executive and proposes to make payment based on that policy when the executive leaves. The executive may accept the payment. Under these circumstances it is clear that the severance pay is in payment for past services not in anticipation of the future services for the Government.

§ 73.735–504 Gifts to official superiors.

An employee shall not solicit a contribution from another employee for a gift to an official superior, make a donation as a gift to an official superior, or accept a gift from an employee receiving less pay than himself or herself. 5 U.S.C. 7351. This section does not prohibit a voluntary gift of nominal value or donation in nominal amount made on a special occasion such as marriage, illness or retirement.

§ 73.735–505 Acceptance of awards and prizes.

(a) Employees may accept awards, including cash awards, given in recognition of a meritorious public contribution or achievement. However, if there is any indication that the award may improperly influence the employee in the performance of his or her offical duties, advice about the acceptance of it should be sought from a deputy ethics counselor. Also, an employee may not accept an award from an organization which the employee knows, or should know, has a contractual or other business arrangement with, or is regulated by, the principal operating component, or a sub-unit, in which he or she is employea or with respect to which the employee has official duties, unless acceptance is approved by the head of the employee's principal operating component. The head of the component may not approve acceptance unless he or she is satisfied that no actual conflict of interest would result.

(b) Employees may generally accept trophies, entertainment, rewards, and prizes given to competitors in contests or events which are open to the public.

(c) Employees may not accept gifts, awards, decorations or other things of value from a foreign government except as provided in § 73.735–506.

§ 73.735–506 Gifts and decorations from foreign governments.

(a) An employee may not request or otherwise encourage the tender of a gift or decorations from a foreign government or official thereof.

(b) An employee may accept from a foreign government:

(1) A gift which is in the nature of medical treatment or an educational scholarship;

(2) A tangible gift of minimal value tendered or received as a mark of courtesy; ("Minimal value" means a retail value in the United States at the time of acceptance of not more than one hundred dollars, unless the Administrator of the General Services Administration adjusts the value by regulation.) or

(3) A tangible gift of more than minimal value when it appears that to

refuse the gift would be likely to cause offense or embarrassment or otherwise adversely affect the foreign relations of the United States. However, the acceptance of such a gift would be on behalf of the United States and the gift would become the property of the United States. See the Department's General Administration Manual, Chapter 20-25 for information regarding the disposition of a gift accepted under these circumstances.

(c) An employee may also accept from a foreign government gifts of travel or expenses for travel (such as transportation, food and lodging) that take place entirely outside the United States and are of more than minimal value, if such acceptance is consistent with the interests of the United States and is approved by the travel approving authority in accordance with the Department's Travel Manual. See General Administration Manual, Chapter 20-25 for a requirement to report such travel.

(d) An employee may accept, retain, and wear a decoration tendered in recognition of active field service in time of combat operations or awarded for other outstanding or unusually meritorious performance, subject to the approval of the Secretary or his or her designee.

(e) Members of an employee's family and household are also subject to the regulations in this section. A member of an employee's family and household is a relative by blood, marriage or adoption who is a resident of the household. However, if a member of an employee's family and household is employed by another agency of the Government, the offer or acceptance of a gift shall be treated under the regulations of that agency.

(f) For purposes of this section "foreign government" means:

(1) Any unit of foreign government authority including any foreign national, state, local and municipal government;

(2) Any international or multinational organization whose membership is composed of any unit of foreign government described in paragraph (f)(1) of this section; or

(3) Any agent or representative of any such unit or organization when acting as such agent or representative. (5 U.S.C. 7342)

§ 73.735-507 Acceptance of travel and subsistence

(a) Except as provided in paragraph (b) of this section, employees may accept accommodations, subsistence, and travel in cash or in kind in connection with official travel for attendance at meetings, conferences, training in non-Governmental facilities or for performing advisory services, if approved in accordance with the provisions of the HHS Travel Manual. (5 U.S.C. 4111; 42 U.S.C. 3506)

(b) Employees may not accept accommodations, subsistence, or travel in cash or in kind in connection with official travel from a non-Governmental source with which they have official dealings unless Government or commercial travel and/or accommodations are not available. If travel and/or subsistence is accepted for official travel under these circumstances, such acceptance and the basis for it must be reported in writing to the Head of the Principal Operating Component or Assistant Secretary for Management and Budget for the Office of the Secretary.

§ 73.735-508 Other prohibitions.

Employees shall avoid any action whether or not specifically prohibited by this part, which might result in or create the appearance of:

(a) Using public office for private gain;

(b) Giving preferential treatment to any person;

(c) Impeding Government efficiency or economy;

(d) Losing complete independence or impartiality in the performance of their Government duties;

(e) Making a Government decision outside official channels; or

(f) Affecting adversely the confidence of the public in the integrity of the Government.

Subpart F—Political Activity

§ 73.735-601 Applicability.

(a) All employees in the Executive Branch of the Federal Government, including non-career employees, are subject to basic political activity restrictions in subchapter III of Chapter 73 of Title 5, United States Code (the former Hatch Act) and Civil Service Rule IV. Employees are individually responsible for refraining from prohibited political activity. Ignorance of a prohibition does not excuse a violation. This subpart summarizes provisions of law and regulation concerning political activity of employees. The Federal Personnel Manual and other publications of the Office of Personnel Management contain more detailed information on this subject. These may be reviewed in Department personnel offices, or will be made available by the Ethics Counselor, or the deputy counselor for the employee's organizational component.

(b) The Secretary and Under Secretary are exempt from the prohibitions concerning active participation in political management and political campaigns. Also exempt are other officials of the Department, except the Inspector General and Deputy Inspector General, who are appointed by the President by and with the advice and consent of the Senate, and who determine policies to be pursued by the United States in the nationwide administration of Federal laws.

(c) Intermittent employees are subject to the restrictions when in active duty status only and for the entire 24 hours of any day of actual employment.

(d) Employees on leave, on leave without pay, or on furlough even though an employee's resignation has been accepted, are subject to the restrictions. Separated employees who have received a lump-sum payment for annual leave are not subject to the restriction during the period covered by the lump-sum payment or thereafter, provided they do not return to Federal employment during that period. Employees are not permitted to take a leave of absence to work with a political candidate, committee, or organization or to become a candidate for office with the understanding that they will resign their position if nominated or elected.

(e) Employees are accountable for political activity by another person acting as their agent or under the employee's direction or control, if they are thus accomplishing indirectly what they may not lawfully do directly and openly.

(f) Though officers in the Public Health Service Commissioned Corps are not subject to the restrictions in Subchapter III of Chapter 73 of Title 5, United States Code, the provisions of this subpart apply to them.

§ 73.735-602 Permissible activities.

(a) Section 7324 of Title 5, United States Code, provides that employees have the right to vote as they please and to express their opinions on political subjects and candidates. Generally, however, employees are prohibited from taking an active part in political management or political campaigns or using official authority or influence to interfere with an election or affect its results. There are some exemptions from the restrictions of the statute:

(1) Employees may engage in political activity in connection with any question not specifically identified with a national or State political party. They also may engage in political activity in connection with an election, if none of the candidates represents a party any of whose candidates for presidential elector received votes at the last preceding election at which presidential electors were selected.

(2) An exception relates to political campaigns within, or in communities adjacent to, the District of Columbia, or in communities the majority of whose voters are employees of the Federal government. Communities to which the exception applies are specifically designated by the Office of Personnel Management. Information regarding the localities and the conditions under which the exceptions are granted may be obtained from personnel offices or the Department Counselor or deputy counselors.

(b) A covered employee is permitted to:

(1) Register and vote in any election;

(2) Express his or her opinion as an individual citizen privately and publicly on political subjects and candidates;

(3) Display a political picture, sticker, badge or button;

(4) Participate in the nonpartisan activities of a civic, community, social, labor, or professional organization, or of a similar organization;

(5) Be a member of a political party or other political organization and participate in its activities to the extent consistent with law;

(6) Attend a political convention, rally, fund raising function; or other political gathering;

(7) Sign a political petition as an individual citizen;

(8) Make a financial contribution to a political party organization;

(9) Take an active part, as an independent candidate, or support of an independent candidate, in a partisan election in localities identified as permissible for such activities by the Office of Personnel Management;

(10) Take an active part, as a candidate or in support of a candidate, in a nonpartisan election;

(11) Be politically active in connection with a question which is not specifically identified with a political party, such as a constitutional amendment, referendum, approval of a municipal ordinance or any other question or issue of a similar character;

(12) Serve as an election judge or clerk, or in a similar position to perform nonpartisan duties as prescribed by State or local law; and

(13) Otherwise participate fully in public affairs, except as prohibited by law, in a manner which does not materially compromise his or her efficiency or integrity as an employee or the neutrality, efficiency, or integrity of his or her agency.

(c) The head of a principal operating component may prohibit or limit the participation of an employee or class of employees of his or her component in an activity permitted by paragraph (b) of this section, if participation in the activity would interfere with the efficient performance of official duties, or create a conflict or apparent conflict of interest.

§ 73.735–603 Prohibited activities.

(a) The following are prohibited activities:

(1) Serving as an officer of a political party, a member of a national, State or local committee of a political party, an officer or member of a committee of a partisan political club, or being a candidate for any of these positions;

(2) Organizing or reorganizing a political party organization or political club;

(3) Directly or indirectly soliciting, receiving, collecting, handling, disbursing, or accounting for assessments, contributions, or other funds for a partisan political purpose or in connection with a partisan election;

(4) Organizing, selling tickets to, seeking support for, or actively participating in a fund-raising activity of, a political party or political club;

(5) Taking an active part in managing the political party campaign of a candidate for public office or political office;

(6) Being a candidate for, or campaigning for, an elective public office, except as permitted in § 73.735–602(b)(9);

(7) Taking an active part in an organized solicitation of votes in support of or in opposition to a candidate for public office or political party office;

(8) Acting as recorder, watcher, challenger, or similar officer at the polls on behalf of a political party or candidate in a partisan election;

(9) Driving voters to the polls on behalf of a political paty or a candidate in a partisan election;

(10) Endorsing or opposing a candidate in a partisan election in a political advertisement, a broadcast, campaign literature, or similar material;

(11) Serving as a delegate, alternate, or proxy to a political party convention;

(12) Addressing a State or national convention or caucus, or a rally or similar gathering of a political party, in support of or in opposition to a candidate for public or political party office, or on a partisan political question; and

(13) Initiating or circulating a nominating petition for a candidate in a partisan election.

(b) In addition, certain political activities are prohibited by Federal criminal law:

(1) Officers and employees may not directly or indirectly solicit or receive, or be in any way involved in soliciting or receiving, any assessment, subscrip-

tion or contribution for any political purpose whatever from another officer or employee. This prohibition extends to one who acts as a mere agent or messenger for the purpose of turning the contribution over to a political organization. 18 U.S.C. 602.

(2) All persons, whether employees or not, are prohibited from soliciting in any manner, or receiving a contribution of, money or a thing of value, in any room or building occupied in the discharge of official duties by any officer or employee of the United States. 18 U.S.C. 603. This prohibition extends to the sending of a letter soliciting political contributions for delivery in a Government building.

(3) No officer or employee may directly or indirectly give to any other officer, employee or person in the service of the United States, any money or other thing of value to be applied to the promotion of any political objective. 18 U.S.C. 607.

(4) Discrimination for giving or withholding any contribution for any political purpose and discrimination based on political influence or recommendations is prohibited.

(c) Various other laws prohibit certain activities in connection with political campaigns and elections. They include:

(1) Intimidating, threatening, or coercing voters in Federal elections (18 U.S.C. 594).

(2) Using official authority in interfering with a Federal election by a person employed in any administrative position by the United States or by any department, independent establishment, or agency of the United States or by any State, agency, or political subdivision thereof in connection with any activity financed in whole or in part by Federal funds (18 U.S.C. 595).

(3) Promising Federal employment, compensation, or any benefit from Federal funds, in return for political activity or support (18 U.S.C. 600).

(4) Depriving anyone of employment, compensation, or any benefit derived from Federal relief or work relief funds on account of race, creed, color, or political activity (18 U.S.C. 601).

(5) Soliciting, assessing, or receiving subscriptions or contributions for political purpose from anyone on Federal relief or work relief (18 U.S.C. 604).

Subpart G—Outside Activities

§ 73.735–701 General provisions.

(a) Outside employment may be appropriate when it will not adversely affect performance of an employee's official duties and will not reflect discredit on the Government or the Department. Such work may include civic, charitable, religious, and community undertakings. There are certain types of outside work, however, which give rise to a real or apparent conflict of interest. Some of these are prohibited by law. Others are prohibited by regulation, as discussed in paragraph (b) of this section, or by criteria developed by heads of operating components for application within a particular component. All of these provisions are binding, but they do not necessarily include all possible conflicts of interest. In all instances, good judgment must be used to avoid a conflict between an employee's Federal responsibilities and outside activities.

(b) An employee shall not engage in outside employment or other outside activity not compatible with the full and proper discharge of the duties and responsibilities of his or her Government employment whether or not in violation of any specific provision of law. Incompatible activities include, but are not limited to:

(1) Acceptance of a fee, compensation, gift, payment of expense, or any other thing of monetary value in any circumstances in which acceptance may result in, or create the appearance of, conflicts of interest;

(2) Outside employment which tends to impair the employee's mental or physical capacity to perform Government duties and responsibilities in an acceptable manner;

(3) Work which identifies the Department or any employee in his or her official capacity with any organization commercializing products relating to work conducted by the Department, or with any commercial advertising matter, or work performed under such circumstances as to give the impression that it is an official act

of the Department or represents an official point of view;

(4) Outside work or activity that takes the employee's time and attention during his official work hours.

(c) An employee shall not receive any salary or anything of monetary value from a private source as compensation for services to the Government. For example, a Department employee may be called upon, as a part of his or her official duties, to participate in a professional meeting sponsored by a non-Government organization, or to contribute a paper or other writing prepared on official time for publication under non-Government auspices. The employee must not accept an honorarium or fee for such services, even though the organization accepting the service customarily makes such a payment to those who participate. Nor may the employee accept a contribution to some charity, educational institution, or the like, in appreciation of the services furnished by the Department employee who cannot accept the usual payment. All offers to make such a contribution must be refused. Any employee with whom such a question is raised shall explain that the service involved was provided as an official action of the Department and is authorized by law. Under these circumstances, it is inappropriate for any payment to be made, even indirectly and to a third party, for services which are furnished without charge by the Government.

(d) Other than as provided in paragraph (c) of this section, employees may receive compensation or other things of monetary value for any lecture, discussion, writing or appearance the subject matter of which is in part devoted to the responsibility, programs or operations of the Department so long as the activity is undertaken in a personal capacity, is not performed as official duty, is not done while on official time, and does not create a conflict of interest or appearance of conflict of interest. However, such activities are considered outside employment and may be undertaken only as provided in this subpart.

(e) This section does not restrict the acceptance of compensation or other things of monetary value for any lecture, discussion, writing or appearance, the subject matter of which is not devoted to the responsibilities, programs, or operations of the Department and which are undertaken in a private capacity and in accordance with §§ 73.735–704, 73.735–705, or 73.735–706.

(f) Federal law limits the amount of honorarium that may be paid any employee for any one speech, writing or appearance to $2,000.00 (not to include amounts for actual travel and subsistence expenses for the employee and his or her spouse) and an aggregate of $25,000.00 in any calendar year. This limitation applies to such activities whether or not the subject matter is related to the responsibilities, programs or operations of the Department. (2 U.S.C. 441i) The term "honorarium" means payment of money or other thing of value whether made gratuitously or as a fee for an appearance, speech or article but does not include salary or compensation made for services rendered on a continuing basis, such as for teaching, or as proceeds from the sale of a book or similar undertaking.

(g) An employee who is a Presidential appointee covered by section 401(a) of Executive Order 11222 shall not receive compensation or anything of monetary value for any consultation, lecture, discussion, writing or appearance, the subject matter of which is devoted substantially to the responsibilities, programs, or operations of his or her component, or which draws substantially on official data or ideas which have not or will not on request become public information. .

(h) Application of these general provisions to some specific activities is discussed below.

§ 73.735–702 Criminal prohibitions on outside activities.

(a) An employee may not, with or without compensation, represent another before any Government agency, court or commission in connection with any proceeding, application, request for a ruling, contract, claim or other particular matter in which the United States is a party or has a direct and substantial interest. (18 U.S.C. 203 and 205)

(b) An employee may not act as agent or attorney for anyone else in prosecuting any claim against the United States (18 U.S.C. 205).

(c) As an exception to the above, if it is not inconsistent with the performance of his or her duties, an employee may act without compensation as an agent or attorney for another employee, or a person under active consideration for Federal employment, who is the subject of disciplinary, loyalty, or other personnel administration proceedings in connection with those proceedings at the administrative level. For example, an employee may represent another employee who is the subject of disciplinary action, or the complainant in a discrimination proceeding, at all stages within the Department and before the Merit Systems Protection Board or Equal Employment Opportunity Commission but not in Federal Court. It would be inconsistent with the performance of official duties for a supervisor to represent subordinate employees.

(d) The law and these regulations do not prohibit an employee from acting, with or without compensation, as agent or attorney for his or her parents, spouse, child or any person for whom, or estate for which, he or she is acting as fiduciary provided that the head of the principal operating component or his or her designee approve. Such approval, if granted, must be granted in accordance with the procedures for approval of outside activity. However, the employee may not do so if the particular matter is one in which he or she has participated personally and substantially or which is his or her official responsibility. (18 U.S.C. 205).

§ 73.735–703 Statutory prohibitions related to employment by a foreign government.

Employees, including officers in the Public Health Service (PHS) Commissioned Corps and retired officers of the Regular Commissioned Corps of the PHS, may not, without the consent of Congress, be employed by a foreign government or agency of a foreign government (Art. I, Sec. 9, U.S. Const.). Congress has consented to such employment by Reserve Commissioned Officers of the PHS not on active duty and by Retired Regular Commissioned Officers (37 U.S.C. 801 note) if approved under regulations of the Department of State. 22 CFR Part 3a.

§ 73.735–704 Professional and consultative services.

(a) Employees may engage in outside professional or consultative work only after meeting certain conditions. Except as provided in §§ 73.735–705 and 73.735–706 for activities discussed in those sections, the conditions which must be met are:

(1) The work is not to be rendered, with or without compensation, to organizations, institutions, or state or local governments with which the official duties of the employee are directly related, or indirectly related if the indirect relationship is significant enough to cause the existence of conflict or apparent conflict of interest; or

(2) The work is not to be rendered for compensation to help a person, institution, or government unit prepare or aid in the preparation of grant applications, contract proposals, program reports, and other material which are designed to become the subject of dealings between the institutions or government units and the Federal Government. All requests to perform consultative services, either compensated or uncompensated, for institutions or government units which have recently negotiated or may in the near future seek a contract or grant from this Department must be carefully appraised to avoid any conflict or apparent conflict of interest.

(b) Advance administrative approval in accordance with § 73.735–708 of this subpart must be obtained. Such approval is required whether or not the services are for compensation, and whether or not related to the employee's official duties.

(c) For the purpose of this section "professional and consultative work" is performance of work requiring knowledge of an advanced type in a field of science or learning customarily acquired by a course of specialized instruction and study in an institution of higher education, or hospital which requires the exercise of judgment and discretion in its performance and is primarily intellectual in nature as opposed to manual, mechanical or physical work.

(d) Membership on a Board of Directors, Board of Regents, Board of Trustees, Planning Commission, Advisory Council or Committee, or on any similar body which provides advice, counsel, or consultation, shall be considered outside consultative services for which advance administrative approval is required.

§ 73.735–705 Writing and editing.

(a) Employees are encouraged to engage in outside writing and editing whether or not done for compensation, when such activity is not otherwise prohibited. Such writing and editing, though not a part of official duties, may be on a directly related subject or entirely unrelated. Certain conditions must be met in either case, however, and certain clearances or approvals are prescribed according to the content of the material as set forth in paragraphs (b) through (e) of this section.

(b) Conditions applying to writing and editing done not as a part of official duties.

(1) The following conditions shall apply to all writing and editing whether related or unrelated to the employee's official duties:

(i) Government-financed time or supplies shall not be used by the author or by other Government employees in connection with the activity; and

(ii) Official support must not be expressed or implied in the material itself or advertising or promotional material, including book jackets and covers, relating to the employee and his or her contribution to the publication.

(2) If the writing or editing activity is unrelated to the employee's official duties or other responsibilities and programs of the Federal government, the employee must:

(i) Make no mention of his or her official title or affiliation with the Department, or

(ii) Use his or her official title or affiliation with the Department in a way that will not suggest or convey official endorsement of the work.

(3) If the writing or editing activity is related to the employee's official duties or other responsibilities and programs of the Federal government, the employee must:

(i) Make no mention of his or her official title or affiliation with the Department, or

(ii) Use his or her official title or affiliation with the Department and a disclaimer as provided in paragraph (e) of this section, or

(iii) Submit the material for clearance within the operating component, under procedures established by the component. When clearance is denied at any lower level, the employee shall have recourse for review up to the head of the principal operating component. This clearance will show there are no official objections to the activity and the employee may then use his or her official title or affiliation with the Department usually without a disclaimer.

(c) *Disclaimers.* (1) Except where the requirement for disclaimer is waived as a result of official clearance, disclaimers shall be used in all writing and editing related to the employee's official duties or other responsibilities and programs of the Federal government:

(i) In which the employee identifies himself or herself by official title or affiliation with the Department, or

(ii) When the prominence of the employee or the employee's position might lead the public to associate him or her with the Department, even without identification other than name.

(2) Disclaimers shall read as follows unless a different wording is approved by the Assistant General Counsel, Business and Administrative Law Division, Office of the General Counsel: "This (article, book, etc.) was (written, edited) by (employee's name) in (his or her) private capacity. No official suport or endorsement by (name of operating component or of Department) is intended or should be inferred."

(d) *Advance approval.* Advance approval is required in accordance with

§ 73.735-708 of this subpart when one or more of the following conditions apply:

(1) Any Government information is used which is not available on request to persons outside the Government;

(2) Material is written or edited which pertains to subject matter directly related to an employee's official duties; (This includes editing for scientific or professional journals which is related to his or her official duties.)

(3) Material is written or edited which pertains to any Government-sponsored research or other studies for which clinical case records or other material of a confidential nature are used or to which access is limited for persons outside the Government. Such use will not be permitted unless made under safeguards established by the operating component to retain the confidentiality of the material, and such use is determined to be in the public interest.

§ 73.735-706 Teaching, lecturing, and speechmaking.

(a) Employees are encouraged to engage in teaching and lecturing activities which are not part of their official duties when certain conditions are met. These conditions, which apply to outside teaching and lecturing (including giving single addresses such as commencement and Memorial Day speeches) whether or not done for compensation, are:

(1) No Government-financed time, or Government supplies not otherwise available to the public, are used in connection with such activity;

(2) Government travel or per diem funds are not used for the sole purpose of obtaining or performing such teaching or lecturing;

(3) Such teaching or lecturing is not dependent on specific information which would not otherwise be available to the public;

(4) Teaching, lecturing, or writing may not be for the purpose of the special preparation of a person or class of persons for an examination of the Office of Personnel Management or Board of Examiners for the Foreign Service, that depends on information obtained as a result of the employee's Government employment, except when that information has been made available to the general public or will be made available on request;

(5) Such activities do not involve knowingly instructing persons on dealing with particular matters pending before Government organizations with which the employee is associated in an official capacity;

(6) Advance approval is obtained when required by paragraph (b) of this section.

(b) Advance approval. Advance approval must be obtained in accordance with § 73.735-708 of this subpart before an employee may:

(1) Teach or lecture for an institution which has or is likely to have official dealings with the bureau or comparable organizational unit in which he or she is employed;

(2) Use, for teaching or lecturing purposes, clinical case records or other material of a confidential nature or to which access is limited for persons outside the Government. Such use will not be permitted unless made under safeguards established by the operating component to retain the confidentiality of the material, and such use is determined to be in the public interest.

§ 73.735-707 Holding office in professional societies.

(a) Employees may be members of professional societies and be elected or appointed to office in such a society. Activity in professional associations is generally desirable from the point of view of both the Department and the employee. Employees shall avoid, however, any real or apparent conflict of interest in connection with such membership. For example, they must not:

(1) Directly or indirectly commit the Department or any portion of it on any matter unless such action is taken in an official capacity;

(2) Permit their names to be attached to documents the distribution of which would be likely to embarrass the Department; or

(3) Serve in capacities involving them as representatives of non-Government organizations in dealing with the Government.

(b) In undertaking any office or function beyond ordinary membership in a professional association, a Department employee must obtain advance approval in accordance with § 73.735–708 of this subpart in any situation in which his or her responsibilities as an officer would relate to his or her official duties or would create a real or apparent conflict of interest with responsibilities as a Department employee. For example, advance administrative approval must be obtained:

(1) Before an employee who is responsible for review and approval of grants or contracts, or is in a supervisory position over those who conduct review and approval, may hold office, or be a trustee or member of the governing board, or the chairman or member of a committee, in any organization which has or is seeking a grant or contract with the bureau or comparable organizational unit in which he or she is employed;

(2) Before an employee may hold office in an organization which customarily expresses publicly views on matters of legislative or administrative policy within the specific areas of concern to the Department.

§ 73.735–708 Administrative approval of certain outside activities.

(a) *Scope.* As specified in § 73.735–704 through 707, an employee is required to obtain advance administrative approval to engage in the following outside activities:

(1) Certain writing or editing activities;

(2) Certain types of teaching and lecturing;

(3) All professional and consultative services;

(4) Any other outside activity for which the head of a principal operating component or the head of a subunit of a principal operating component imposes internal requirements for administrative approval; and

(5) Certain office-holding activities in professional societies.

(b) *Requests for Administrative Approval.* An employee seeking to engage in any of the activities for which advance approval is required shall make a written request for administrative approval a reasonable time before beginning the activity. (See § 73.735–202(e)(1)). This request should be directed to the employee's supervisor who will forward it to the official authorized to approve outside work requests for the employee's component. The request should include the following information:

(1) Employee's name, position title, grade or rank;

(2) Nature of the activity, fully describing the specific duties or services for which approval is requested;

(3) Name and business of person or organization for which work will be done, or statement that work will be self-employment. If self-employment, employee must state whether activity will be conducted alone or with partners;

(4) Place where work will be performed;

(5) Estimated total time to be devoted to activity. If on a continuing basis, indicate estimated time per year and the anticipated termination date;

(6) Whether services can be performed entirely outside of usual duty hours. If not, the estimated number of hours absent from work should be indicated;

(7) Method or basis of compensation if any (e.g., fee, per diem, per annum, or other).

(8) Where an employee seeks approval to provide consultative or professional services to organizations including governments which have been awarded or may apply for a Federal grant or contract, the request shall also include full details on any aspect of the professional and consultative services which could relate in any way, either directly or indirectly, to grant applications, contract proposals, program reports, and other material which are designed to become the subject of dealings between the grantee or contractor and the Government. (See § 73.735–704(a)(2))

(c) The Department Ethics Counselor will review and approve outside work requests for Executive level officers, non-career executives, deputy ethics counselors, and Schedule C employees in the Office of the Secretary.

(d) *Granting Approval of Certain Activities.* The approving official shall review each request submitted under paragraph (b) of this section, and appraise each request on the basis of the standards of this part and all other applicable laws, regulations or internal rules of the principal operating component or sub-unit thereof. He or she should consult with a deputy ethics counselor or the Department Ethics Counselor in all cases that raise a difficult or novel question of law or fact. The approving official shall approve or disapprove each request and communicate his or her decision in writing to the employee.

§ 73.735–709 Annual reporting of outside activities.

By September 10 of each year the approving official shall require a report from each person for whom outside work has been approved during the past year. The report shall show:

(a) For the 12 months just past (ending August 31):

(1) Whether the anticipated work was actually performed for the person or organization named in the request for approval;

(2) Actual amount of time spent on the activity.

(b) For the forthcoming 12 months (ending August 31):

(1) Whether it is anticipated that the outside work will continue;

(2) Whether any change is anticipated with respect to information supplied in accordance with the original request on which approval was based.

§ 73.735–710 Maintenance of records.

The official responsible for the administrative aspects of these regulations (§ 73.735–202) shall make provisions for the retention and filing of requests for approval of outside work (or copies of such requests), a copy of the notification of approval or disapproval, and the annual report.

Subpart H—Financial Interests

§ 73.735–801 Participation in matters affecting a personal financial interest.

(a) An employee shall not participate personally and substantially as a Government employee in a matter in which any of the following individuals or organizations has a financial interest:

(1) The employee;

(2) The employee's spouse;

(3) The employee's minor child;

(4) An organization in which the employee serves as an officer, director, trustee, partner, or employee; or

(5) A person or organization with which the employee is negotiating for prospective employment or has an arrangement for prospective employment. Criminal penalties may be imposed under 18 U.S.C. 208 for violations of the prohibition.

(b) Applying the provision of 18 U.S.C. 208:

(1) A "financial interest" is any interest of monetary value which may be directly and predictably affected by the official action of an employee. There is no minimum amount of value or control that constitutes a financial interest.

Example 1: An employee owns a single share of stock in a widely-held corporation. If the corporation is likely to be affected by a matter in which the employee participates as a Government official, the employee may violate 18 U.S.C. 208.

Example 2: An employee has a paid part-time position with a non-federal organization. If the organization is likely to be affected by a matter in which the employee participates as a Government official, the employee would violate 18 U.S.C. 208.

(2) The prohibition of 18 U.S.C. 208 applies to personal and substantial involvement by an employee in a matter, exercised through decision, approval, disapproval, recommendation, investigation, giving advice, or other significant effort regarding the matter.

Example 1: An employee is a member of a panel that evaluates proposals for contracts and makes recommendations as to their award. If the employee's spouse owns stock in a company which submits a proposal that is reviewed by the panel, the employee would violate 18 U.S.C. 208 even though the panel recommendation may be rejected by the contracting officer.

Example 2: An employee is on a leave of absence from a university. He or she would violate 18 U.S.C. 208 by participating in the drafting of regulations which would have a "direct and predictable effect" upon universities in general and, therefore, upon the employee's university.

(3) An employee must know that the financial interest exists in order to violate 18 U.S.C. 208.

Example: An employee inherited a beneficial interest in a trust. He or she does not, however, have actual knowledge of the specific property held by the trustee. If the trust contains stock in a corporation which may be affected by the employee's official actions, he or she would not violate 18 U.S.C. 208 in taking official action affecting the corporation.

(4) Negotiation for prospective employment includes both an indication of interest on the part of the employee in working for an organization and an affirmative action on the part of the organization to show consideration of the employee.

Example 1: An employee of the Department sends resumes and cover letters to fifty prospective employers, all of whom regularly have dealings with HHS. Forty employers do not respond; however, ten respond with cordial form letters stating that the employee's resume will be retained for future reference. For purposes of the 18 U.S.C. 208 prohibition, the employee is negotiating for prospective employment at the time he or she sends resumes.

Example 2: At a site visit to a grantee institution, an employee who is officially responsible for a grant to that institution informs an officer of the institution that he or she is seeking a new position outside HHS. The grantee subsequently makes a conditional offer of employment to the employee who promptly responds by asking for an opportunity to discuss salary and related matters. Under these circumstances, a negotiation for prospective employment is underway.

(c) An employee may obtain approval to participate in his or her official capacity in a matter in which he or she has a direct or indirect financial interest, if the interest is not so substantial as to affect the integrity of his or her official duties. An employee who believes that such participation is warranted should follow the procedures in § 73.735-804.

(d) An employee convicted of violating 18 U.S.C. 208 may be fined up to $10,000, or imprisoned up to two years, or both.

§ 73.735-802 Executive order prohibitions.

(a) *Basic prohibition of Executive Order 11222.* (1) An employee shall not have a direct or indirect financial interest that conflicts substantially, or appears to conflict substantially, with his or her duties as a Federal employee.

(2) An employee need not have a financial interest that actually conflicts with his or her duties to violate the prohibition of E.O. 11222. Any financial interest that could reasonably be viewed as an interest which might compromise the employee's integrity, whether or not this is in fact true, is subject to this prohibition.

(3) Except as provided in § 73.735-802 (b) and (c), an employee who has an indirect financial interest in a business entity through the ownership of shares in a widely-held mutual fund or other regulated investment company will not violate E.O. 11222. Stocks in business entities held by an intermediary such as a mutual fund are generally too remote or inconsequential to affect the integrity of an employee's services.

(b) *Employees in regulatory activities.* (1) An employee who is working in a regulatory activity shall not have a financial interest in any company whose business activities are subject to the regulations of the particular activity with which the employee is associated, unless the regulated activities of the company are an insignificant part of its total business operations.

(2) An employee working in a regulatory activity may not hold shares in a mutual fund or other regulated investment company which specializes in holdings in industries that are regulated by the particular activity in which he or she is employed.

Example: An employee working for the Bureau of Laboratories, Center for Disease Control, may not hold shares in a regulated investment company which specializes in holdings that include medical testing laboratories.

(c) Employees having procurement or contracting responsibilities.

(1) An employee who serves as a procurement or contracting officer shall not have a financial interest in a company or companies with which he or she in the course of his or her official duties would be likely to have procurement or contracting relationships.

(2) A procurement or contracting officer may not hold shares in a mutual fund or other regulated investment company that specializes in holdings in industries with which such officer would be likely to have procurement or contracting relationships.

Example: A contracting officer in the Social Security Administration owns shares in the XYZ Mutual Fund which specializes in stock in firms manufacturing electronic data processing equipment. Ownership of XYZ Mutual Fund shares would be prohibited in this instance. On the other hand, a contracting officer for a Public Health Service hospital, who is not likely to have responsibility for major contracts relating to electronic data processing, could hold such shares.

§ 73.735–803 Prohibition against involvement in financial transactions based on information obtained through Federal employment.

An employee shall not engage in, directly or indirectly, a financial transaction as a result of, or in primary reliance upon, any information gained through his or her official duties. Information gained through official duties are those facts and other data that relate to the employee's official duties or to the functions of the employing component and would not be available to the employee were he or she not an officer of the Federal government.

Example 1: An employee working part-time for a consulting firm that does no busines with the employee's principal operating component, in the area of health care planning advises it, based upon his or her knowledge of a new health care planning program about to be initiated by the Public Health Service. The employee's knowledge of the program was acquired solely through reading policy statements and other PHS literature available to the public under the Freedom of Information Act. In such case, the employee would not violate this regulation if the outside activity was otherwise approvable under Subpart G.

Example 2: A contracting officer with detailed knowledge of a negotiated procurement contract invests in a corporation that is likely to indirectly profit from the award of that contract. The officer's decision to invest is based upon technical details of the successful contract proposal that would not otherwise be available to a private citizen. The officer would violate this regulation in such a situation.

§ 73.735–804 Waiver of the prohibitions in this subpart.

(a) An employee may request approval to participate in his or her official capacity in a matter in which he or she has a direct or indirect financial interest if the employee believes the interest is so remote and inconsequential that it would not affect the integrity of his or her official duties. Also an employee who has a financial interest that would otherwise be prohibited under these regulations may request an exemption from the prohibition for the reason stated in the preceding sentence.

(b) The request shall be in writing and shall include the following information:

(1) Employee's name, occupational title, grade or rank and Federal salary;

(2) Full description of financial interest: including whether ownership, service as officer, partner, etc.;

(3) Business or activity in which financial interest exists;

(4) Description of official matter in which employee is requesting approval to participate;

(5) Basis for requesting determination that the interest is "not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect." (If based on a small total value of investment, supply appropriate information on total value, such as total shares held and latest quoted market price. If other basis, explain fully.)

The request should be sent through usual administrative channels to the official responsible for reviewing financial disclosure reports or statements for the employee's organization (Subpart I). That official, after conferring with a deputy ethics counselor or with the Department Ethics Counselor as appropriate, will make a decision about the exemption or exception and inform the employee in writing.

§ 73.735–805 Advice and guidance on conflicts matters.

(a) Whenever an employee has a question about the appropriate course of conduct to be followed in a matter that may involve an actual or apparent conflict of interest, he or she should immediately consult with his or her supervisor or a deputy ethics counselor, or both. If a supervisor who is consulted determines that the matter warrants further consideration, he or she may, in conjunction with the employee, submit the details of the matter, in writing, to the appropriate deputy ethics counselor. These details should include a description of:

(1) The activity, relationship, or interest giving rise to the question posed by the employee;

(2) The duties or official responsibilities of the employee(s) involved;

(3) The nature of the actual or apparent conflict of interest; and

(4) Any other information that may be helpful in reviewing the problem.

(b) Upon receiving the submission of an employee or a supervisor, the deputy ethics counselor will develop any additional information about the matter as necessary, and will confer with the Department Ethics Counselor as appropriate. The Department Ethics Counselor and the head of the principal operating component or his or her designee will be informed of any serious violation of the standards of this subpart or any other conflict of interest law. Questions of first impression or other unusual matters shall be brought to the attention of the Department Ethics Counselor and the head of the principal operating component or his or her designee.

(c) On the basis of all information gathered including, where appropriate, the advice of the Department Ethics Counselor, the deputy ethics counselor will:

(1) Decide that there is no violation or potential violation of the standards of this subpart or any other law and so notify the employee and his or her supervisor in writing; or

(2) Decide that a violation or potential violation of the standards of this subpart or other law has occurred or may occur, and that the employee involved shall take one or more of the steps set forth in § 731.735-904 to resolve the problem and notify the employee and his or her supervisor in writing; or

(3) Decide that, although no violation of this subpart or other law has occurred, the nature of the matter is such that the employee should periodically report any additional information that would require reconsideration of the initial submission.

§ 73.735-806 Documentation and publication of opinions.

(a) The Department Ethics Counselor, deputy ethics counselors, and any other individuals required to be involved in the review and resolution of violations or potential violations of this subpart shall maintain full and accurate documentation of the formal advice and guidance given.

(b) From time to time, the Department Ethics Counselor shall publish summaries of advisory opinions issued by his or her office, deleting, as necessary, any personal identifiers or other information which may give rise to an unwarranted invasion of personal privacy. These summaries shall be distributed to all deputy ethics counselors, heads of principal operating components, and principal regional officials.

(c) From time to time, the Department Ethics Counselor shall publish an index of all summaries issued in accordance with paragraph (b) of this section, and shall distribute these indexes to all deputy ethics counselors and heads of principal operating components who shall in turn make them available for review by supervisors and interested employees.

Subpart I—Reporting Financial Interests

§ 73.735-901 Reporting requirement of the Ethics in Government Act of 1978.

(a) *Applicability.* The following employees and special Government employees shall submit public financial disclosure reports in accordance with the provisions of Title II of the Ethics in Government Act of 1978, Pub. L. 95-521, as amended:

(1) Officers and employees (including consultants who will work more than 60 days in a calendar year) whose positions are classified at GS-16 or above of the General Schedule, or whose basic rate of pay (excluding "step" increases) under other pay

schedules is equal to, or greater than, the rate for GS-16 (step 1);

(2) Members of the uniformed services whose pay grade is 0-7 or above;

(3) Officers and employees in any other positions determined by the Director of the Office of Government Ethics to be of equal classification to GS-16;

(4) Administrative Law Judges;

(5) Employees in the excepted service in positions which are of a confidential or policy-making character, unless their position has been excluded by the Director of the Office of Government Ethics;

(6) Department Ethics Counselor; and

(7) Deputy Ethics Counselors.

An employee who thinks that his or her position has been improperly included under the reporting requirements of this part may obtain a review of that determination by writing to the Department Ethics Counselor.

(b) *Filing Dates.* Employees listed in § 73.735-901 (a) of this subpart shall file a financial disclosure report:

(1) Within 5 days after the transmittal by the President to the Senate of their nomination to a position requiring Senate confirmation, or

(2) Within 30 days after assuming a covered position not requiring Senate confirmation unless the employee has left another covered position listed in § 73.735-901 (a) of this subpart, or

(3) Within 30 days after terminating Federal employment or assuming a position which is not listed in § 73.735-901 (a) of this subpart; and

(4) By May 15 of each calendar year, unless the employee has in that calendar year already submitted a financial disclosure report covering the preceding calendar year.

(c) *Submission of reports.* (1) Executive level officers, non-career executives, deputy ethics counselors and Schedule C employees in the Office of the Secretary who are required to report in accordance with § 73.735-901 (a) of this subpart shall submit their reports to the Department Ethics Counselor.

(2) All other employees required to report in accordance with § 73.735-901 (a) of this subpart shall submit their reports to the reviewing official for their organizational component under procedures described in the Department's Personnel Manual. Personnel offices will keep a list of reviewing officials and will give each covered employee the name of the official to whom his or her report should be sent.

(d) *Review and certification of reports.* (1) Each report submitted in accordance with this section shall be reviewed by the appropriate reviewing official within 60 days of its receipt. Upon reviewing a report and finding that the information contained therein reveals no conflict of interest or other violation of any provision of this part or applicable law, the reviewing officer shall certify the report with his or her signature.

(2) The certification of a report filed in accordance with this section shall have the concurrence of the Office of the General Counsel.

(3) Action to be taken by the reviewing official if the individual is not in compliance with applicable laws and regulations is discussed in § 73.735-903 and § 73.735-904.

§ 73.735-902 Reporting requirements for certain employees not covered by the Ethics in Government Act of 1978.

(a) *Applicability.* The following employees and special Government employees shall submit confidential statements of employment and financial interests in accordance with the provisions of this subpart, provided they are not required to submit financial disclosure reports under § 73.735-901. A list of the positions in this Department whose incumbents are required to file financial interest statements as prescribed by this subpart is available for review in all of the Departments servicing personnel offices.

(1) Officers and employees in positions classified at GS-13 or above (or comparable pay level) who have decision-making responsibility for the following matters:

(i) Contracting or procurement,

(ii) Administering or monitoring grants or subsidies,

(iii) Regulating or auditing private or other non-Federal enterprises, or

(iv) Other activities where the decision or action would have an economic impact on the interest of any non-Federal enterprise.

(2) Incumbents of any other positions designated by the head of the principal operating component, or by the Assistant Secretary for Management and Budget for the Office of the Secretary, to report employment and financial interests in order to protect the integrity of the Government and to avoid possible conflicts of interest. The designation of any such positions below the GS-13 grade must be approved by the Office of Personnel Management.

(3) All experts, consultants, or advisory committee members who are not required to submit a public financial disclosure report in accordance with the Ethics in Government Act except:

(i) Doctors, dentists and allied medical specialists performing services for, or consulted as to the diagnosis or treatment of, individual patients; or

(ii) Veterinarians performing services for or consulted as to care and service to animals.

(b) *Filing dates.* (1) Experts, consultants, and advisory committee members shall file a confidential Statement of Employment and Financial Interest no later than the date employment commences and shall file supplemental statements as necessary to keep all information submitted current and accurate.

(2) Other individuals covered by § 73.735-902 (a) of this subpart shall:

(i) File a confidential statement no later than 30 days after assuming a covered position unless the employee, within 30 days before assuming the position, left another covered position in HHS that is included in § 73.735-901(a) or § 73.735-902(a) of this subpart; and

(ii) Report changes in or additions to the information in the statement as of June 30 of each calendar year, or a different date set by employee's component with authorization by the Office of Personnel Management.

(c) *Submission and review of financial statements.* (1) Heads of principal operating components, the Assistant Secretary for Management and Budget, and principal regional officials for employees under their appointing authority shall establish procedures to ensure that financial statements from covered employees are received and updated on a timely basis and are referred to the appropriate reviewing officials for review and certification. (See § 73.735-202 (e)(1)).

(2) The reviewing official shall review statements to determine whether conflicts of interest or apparent conflicts might arise from the activities reported thereon. If the review discloses no conflict or apparent conflict, the reviewing official shall certify the statement with his or her signature. Action to take if the individual is not in compliance with applicable laws and regulations is discussed in § 73.735-903 and § 73.735-904.

§ 73.735-903 Action if conflicts of interest or possible conflicts are noted.

(a) If after reviewing a financial disclosure report or a financial interest statement, a reviewing official believes that additional information is needed, he or she shall tell the individual submitting such report what additional information is required and the time by which it must be submitted.

(b) If the reviewing official is of the opinion that, on the basis of information submitted, the reporting individual is not in compliance with applicable laws and regulations, he or she shall notify the individual, afford him or her a reasonable opportunity for a written or oral response, and after consideration of such response, determine whether or not the individual is in compliance.

(c) If the reviewing official determines that an individual is not in compliance with applicable laws and regulations, he or she shall notify the individual of that determination in writing and, after an opportunity for personal consultation, determine and notify the individual of the action, including those actions set forth in § 73.735-904, that would be appropriate to assure compliance with such laws and regulations, and the date by which such action should be taken. The action required and the date for taking it shall be determined by the nature of the financial interest or other relationship, the particular circumstances of the reporting individual (including his or her ability to resolve the problem), and other factors which the reviewing official deems relevant. In no case, however, should the date be later than 90 days after the reporting individual is notified of the reviewing official's opinion.

(d) If steps for assuring compliance with applicable laws and regulations are not taken by the date set in paragraph (c) of this section, the matter shall be referred to the Department Ethics Counselor.

§ 73.735–904 Resolution of apparent or actual conflicts of interest.

(a) Disqualification from participating in a particular matter or category of matters is an appropriate method for resolving apparent or actual conflicts of interest when the interest or activity giving rise to the problem:

(1) Bears a direct or indirect relationship to particular, identifiable duties of the employee involved; and

(2) Is not so substantial as to affect or give the appearance of affecting the integrity of the services which the Government may expect of the employee. Whenever disqualification is employed to resolve an apparent or actual conflict of interest, the disqualified employee shall sign a written statement reflecting the scope of the disqualification and the precise nature of the conflicting interest or activity. The reviewing official shall keep a file of all such disqualification statements and shall monitor compliance with these statements on a regular basis.

(b) *Change of assignment* is an appropriate method for resolving apparent or actual conflicts of interest when the interest giving rise to the problem bears a direct or indirect relationship to particular, identifiable duties of the employee involved, and those duties constitute a significant portion of the employee's position.

(c) *Waiver* under 18 U.S.C. 208(b) is an appropriate method for resolving apparent or actual conflicts of interest when:

(1) The employee seeking the waiver reported the financial interest that bears some relationship to his or her official duties, and the reviewing official, in consultation with a deputy ethics counselor or the Department Ethics Counselor, determines that the financial interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from such employee; or

(2) By general rule or regulation published in the FEDERAL REGISTER, the Department has exempted the financial interest from the requirements of 18 U.S.C. 208 and this part as being too remote or too inconsequential to affect the integrity of the Government officers' service.

(d) A *trust* containing a financial interest which may give rise to an apparent or actual conflict of interest is an appropriate method of resolving such conflicts when:

(1) The trust is qualified under section 202(f) of the Ethics in Government Act of 1978 (Pub. L. 95–521), as amended, and subject to the regulations of the Office of Government Ethics; or

(2) In the opinion of the Department's Ethics Counselor, it is sufficiently independent of the employee involved so that the integrity of the employee's services to the Government are not compromised.

(e) *Divestiture* is an appropriate method for resolving actual conflicts of interest when the nature of the financial interest is such that the conflict of interest cannot be adequately resolved by any of the methods set forth in paragraphs (a), (b), (c), and (d) of this section.

(f) *Terminating* an appointment as a method for resolving an actual conflict of interest should be used only when it is clear that no other remedy can be found which would be acceptable to both the Department and the employee. Generally, this method will be employed only in the most extreme cases. Such a termination would be subject to adverse action.

Subpart J—Provisions Relating to Experts, Consultants and Advisory Committee Members

§ 73.735–1001 Coverage.

(a) For purposes of this subpart the title "consultant" will be used to include those who are appointed to serve as experts, consultants or members of advisory committees. All persons who serve as an employee of the Government in the capacity of a consultant are covered by the provisions of this subpart irrespective of:

(1) The title by which designated;

(2) The statutory authority under which services are obtained;

(3) The duration of the period for which services are obtained;

(4) Whether services are obtained by appointment or invitation and acceptance;

(5) Whether services are compensated or rendered without compensation;

(6) Whether or not services are obtained pursuant to a statute excepting employees or special Government employees from conflict of interest statutes.

(b) When the service is for less than 130 days in a service year, experts, consultants, and advisory committee members are included in the group of employees designated by law (18 U.S.C. 202) as "Special Government employees."

§ 73.735-1002 Ethical standards of conduct.

(a) Like other Federal employees, an individual serving in a consultant capacity must conduct himself or herself according to ethical behavior standards of the highest order. In particular, such an individual must:

(1) Refrain from any use of office which is, or appears to be, motivated by a private gain for himself or herself or other persons, particularly those with whom he or she has family, business, or financial ties. The fact that desired gain, if it materializes, will not take place at the expense of the Government makes his or her actions no less improper.

(2) Conduct himself or herself in a manner devoid of any suggestion that he or she is exploiting Government employment for private advantage. A consultant must not, on the basis of any inside information, enter into any speculation or recommend speculation to members of his or her family or business associates, in commodities, land, or the securities of any private company. This injunction applies even though the consultant's duties have no connection whatever with the Government programs or activities which may affect the value of such commodities, land, or securities. He or she should be careful in all personal financial activities to avoid any appearance of acting on the basis of information obtained in the course of his or her Government work.

(3) Refrain from using information not generally available to those outside the Government for the special benefit of a business or other entity by which the consultant is employed or retained or in which he or she has a financial interest. Information not available to private industry should remain confidential in the consultant's hands and not be divulged to his or her private employer or clients. In cases of doubt whether information is generally available to the public, the consultant should confer with the person for whom he or she provides services, with the office having functional responsibility for a specific type of information, or, as appropriate, with the officials designated in § 73.735-202 to give interpretive and advisory service.

(4) Where requested by a private enterprise to act for it in a consultant or advisory capacity and the request appears motivated by the desire for inside information, make a choice between acceptance of the tendered private employment and continuation of his or her Government consultancy. He or she may not engage in both.

(5) Not use his or her position in any way to coerce, or give the appearance of coercing, anyone to provide a financial benefit to him or her or another person, particularly one with whom the consultant has family, business, or financial ties.

(6) Not receive or solicit anything of value as a gift, gratuity, loan, entertainment, or favor for himself or herself or another person, particularly one with whom he or she has family, business, or financial ties if the acceptance would result in loss of complete independence or impartiality in serving the Government. All consultants are subject to the restrictions in § 73.735-506 of this part concerning gifts and decorations from foreign governments.

(b) Consultants may engage in other employment so long as there is no real or apparent conflict between the consultant's private employment and his or her official duties. See § 73.735 Subpart G. The regular employment of a consultant who is a special Government employee is not considered outside work for purposes of Subpart G. Also, the limitation in § 73.735–701(f) regarding the amount of an honorarium that may be received does not apply to special Government employees.

(c) A consultant who has questions about conflicts of interest or the application of the regulations in this part to him or her or to his or her assigned work should make inquiry of the person for whom services are provided. That person may direct the consultant to the Department Ethics Counselor or a deputy ethics counselor for interpretative and advisory services as provided in § 73.735–202.

§ 73.735–1003 Conflicts of interest statutes.

(a) Each consultant should acquaint himself or herself with sections 203, 205, 207 and 208 of title 18, United States Code, all of which carry criminal penalties related to conflicts of interest. The restraints imposed by the four criminal sections are summarized in paragraphs (b) and (c) of this section.

(b) 18 U.S.C. 203 and 205.

(1) These two sections in general operate to preclude a person who works for the Government, except in the discharge of his or her official duties, from representing anyone else before a court or Government agency in a matter in which the United States is a party or has a direct and substantial interest. The prohibition applies whether or not compensation is received for the representation. However, if the individual is a special Government employee, this restriction applies only if:

(i) The representation involves a matter in which the individual has at any time participated personally and substantially in the course of his or her Government employment; or

(ii) The individual has served the Department for more than 60 days in the immediately preceding period of 365 days, and the matter is one which is pending before the Department. This second restraint applies whether or not the matter is one in which the individual participated personally and substantially in his or her Government employment. These two provisions apply to a special Government employee on days when he or she does not serve the Government as well as on the days when services are rendered, and they apply to both paid and unpaid representation.

(2) To a considerable extent the prohibitions of sections 203 and 205 are aimed at the sale of influence to gain special favors for private businesses and other organizations and at the misuse of governmental position or information. In accordance with these aims, a consultant, even when not compelled to do so by sections 203 and 205, should make every effort in his or her private work to avoid any personal contact with respect to negotiations for contracts or grants with the component of the department in which he or she is serving, if the subject matter is related to the subject matter of his or her consultancy or other service. This will not always be possible to achieve where, for example, a consultant has an executive position with his or her regular employer which requires him or her to participate personally in contract negotiations with the department or agency he or she is advising. Whenever this is the case, the consultant should participate in the negotiations for his or her employer only after advising the responsible Government official of his or her involvement in other matters in the Department. In other instances an occasional consultant may have technical knowledge which is indispensable to his or her regular employer in his efforts to formulate a research and development contract or a research grant, and for the same reason, it is in the interest of the Government that the consultant should take part in negotiations for his or her private employer. Again, the individual should participate only after advising the responsible Government official of the relevant facts.

(3) Section 205 permits both the Government and the private employer of a special Government employee to benefit, in certain cases, from his or her performance of work under a grant or contract for which he or she would otherwise be disqualified because of having participated in the matter for the Government or because it is pending in a component in which the consultant had served more than 60 days in the past year. This provision gives the head of a department the authority, notwithstanding any prohibition in either section 203 or 205, to allow a special Governement employee to represent before such department or agency either his or her regular employer or another person or organization in the performance of work under a grant or contract. As a basis for this action, the Secretary must first makes a certification in writing, published in the FEDERAL REGISTER, that it is required by the national interest.

(4) Section 205 contains two other exemptive provisions, which apply to both special and regular Government employees. See § 73.735–702.

(c) 18 U.S.C. 207 applies to individuals who have left Government service. See Subpart N of these regulations.

(d) 18 U.S.C. 208 bears on the activities of Government personnel, including special Government employees, in the course of their official duties. In general, it prevents a Government employee from participating as such in a particular matter in which, to his or her knowledge, he or she, his or her spouse, minor child, partner, or a profit or non-profit enterprise with which he or she is connected has a financial interest. However, the section permits an employee's agency to grant him or her an ad hoc exemption if the interest is not so substantial as to affect the integrity of his or her services. Insignificant interests may also be waived by a general rule or regulation. The matters in which special Government employees are disqualified by section 208 are not limited to those involving a specific party or parties in which the United States is a party or has an interest, as in the case of sections 203, 205 and 207. Section 208 therefore extends to matters in addition to contracts, grants, judicial and quasi-judicial proceedings, and other matters of an adversary nature. Accordingly, a special Government employee, like all government employees, should in general be disqualified from participating as such in a matter of any type the outcome of which will have a direct and predictable effect upon the financial interests covered by the section.

However, the power of exemption may be exercised in this situation if the special Government employee renders advice of a general nature from which no preference or advantage over others might be gained by any particular person or organization. The power of exemption may also be exercised where the financial interests involved are minimal in value.

§ 73.735–1004 Requesting waivers or exemptions.

(a) A consultant may present in writing to the official for whom he or she provides services requests for the waivers or exemptions specified in § 73.735–1003. That official will take, or refer the request for, action as appropriate, and will see that the employee receives advice or decision on his or her request.

(b) A file of all waivers or exemptions granted shall be maintained in such manner that information can be given promptly on individual cases or statistics provided upon request. Generally, these records, together with written advice given in connection with less formal requests concerning questions of ethical standards, are kept with the employee's statement of employment and financial interests or financial disclosure report (§ 73.735–1006).

(c)(1) *Waiver for reviewers from certain multi-campus institutions.* Applicability of the prohibitions of 18 U.S.C. 208(a) and this subpart are hereby waived pursuant to a determination that the interest involved is too remote or too inconsequential to affect the integrity of a special Government employee's review of a funding application or contract proposal from one campus of one of the following multi-campus institutions, where the interest consists solely of employment as a faculty member (including Department Chairman) at a separate campus of the same multi-campus institution:

The University of Alabama system consisting of the University of Alabama, the University of Alabama in Birmingham, and the University of Alabama in Huntsville.

The campuses of the University of California.

The system consisting of Colorado State University, the University of Southern Colorado, and Fort Lewis College.

The Indiana University system consisting of eight universities on nine campuses, with the exception of the system-wide schools: the School of Business; the School of Dentistry; the School of Medicine; the School of Nursing; and the School of Public and Environmental Affairs.

The University of Nebraska system consisting of the University of Nebraska—Lincoln, the University of Nebraska at Omaha, and the University of Nebraska Medical Center.

The campuses of the State University of New York.

The Oregon system of higher education consisting of the University of Oregon, Oregon State University, Oregon Health Sciences University, Portland State University, Western Oregon State College, Southern Oregon State College, Eastern Oregon State College, and the Oregon Institute of Technology.

The campuses of the University of Tennessee.

The separate universities comprising the University of Texas System.

The separate universities comprising the University of Wisconsin System.

(2) *Institutions that are not subject to 18 U.S.C. 208(a) and the subpart, because they are not part of the same organization within the State.* The following State institutions and systems of higher education have been determined to be separate from each other to such a degree that no waiver is necessary in order to permit a faculty member (including Department Chairman) employed by one of the State institutions of higher education to review a funding application or contract proposal from another of the named institutions within that State:

The University of Alabama System and other Alabama State owned institutions of higher education.

The California Community Colleges, the California State Universities and Colleges, and the University of California.

The University of Colorado, Colorado State University, and other Colorado State owned institutions of higher education.

The University of Connecticut, Connecticut State University, the Connecticut Technical Colleges, and the Connecticut Community Colleges.

The University of Illinois, Illinois State University, Western Illinois University, Southern Illinois University, and the Illinois Community Colleges.

The Indiana University and the other Indiana State owned institutions of higher education.

The University of Iowa, and Iowa State University.

The University of Kansas, Kansas State University, Wichita State University, Fort Hays State University, Pittsburg State University, and the Kansas Technological Institute.

Louisiana State University, and other Louisiana State owned institutions of higher education.

The University of Massachusetts, and other Massachusetts State owned institutions of higher education.

The University of Michigan, Michigan State University, and Wayne State University.

The University of Minnesota, the Minnesota State University System, and the Minnesota Community College System.

The University of Missouri, and other Missouri State owned institutions of higher education.

The University of Nebraska, and other Nebraska State owned institutions of higher education.

The State University of New York System, and the City University of New York System.

The University of North Carolina, North Carolina State, and other North Carolina State owned institutions of higher education.

Pennsylvania State University, the University of Pittsburgh, Temple University, Lincoln University, and the other State owned colleges and universities in Pennsylvania.

The University of Texas System, the Texas A&M System, the Texas State University System, the University System of South Texas, the Lamar University System, the University of Houston System, East Texas State University, Stephen F. Austin State University, West Texas State University, Midwestern University, North Texas State University, Texas Southern University, Texas Woman's University, Texas Tech University and Pan American University.

The University of Utah and Utah State University.

[46 FR 7369, Jan. 23, 1981, as amended at 51 FR 15627, Apr. 25, 1986]

§ 73.735–1005 Salary from two sources.

Special government employees are not subject to 18 U.S.C. 209 which prohibits other employees from receiving any salary, or supplementation of Government salary, from a private source as a compensation for services to the Government. This Department will not knowingly pay per diem to a consultant who also receives per diem pay for the same day from another Government agency (in or outside the Department). Erroneous payments in contravention of this provision will be subject to collection, and any consultant who willfully collects double payments may be barred from further employment.

§ 73.735–1006 Reporting financial interests.

(a) Consultants who will work more than 60 days in a calendar year are subject to the provisions of title II of the Ethics in Government Act of 1978 when their rate of pay is equal to or greater than the basic rate for GS-16, Step 1. Such consultants are covered by the reporting requirements of § 73.735–901 of these regulations.

(b) Consultants not subject to the Ethics in Government Act shall file statements of financial interests as provided by § 73.735–902 of these regulations.

§ 73.735–1007 Political activity.

Consultants who serve intermittently are subject to the political activity restrictions of Subchapter III of Chapter 73 of Title 5 U.S.C. and Civil Service Rule IV only on days on which service is rendered and then for the entire 24 hours of such service day. Other consultants are subject to these restrictions at all times.

Subpart K—Special Government Employees Other Than Consultants

§ 73.735–1101 General provision.

Individuals who are designated as special Government employees because of the nature of their services but who are not serving as a consultant, expert, or advisory committee member are subject to the provisions of Subparts B through I of these regulations. However, the provisions of 18 U.S.C. 205, 206, 207, and 208 apply to them only as described in Subpart J. Also, the limitation in § 73.735–701(f) on the amount of an honorarium that may be received does not apply.

Subpart L—Disciplinary Action

§ 73.735–1201 General provisions.

(a) Violations of the regulations contained in the Part may be cause for disciplinary action which could be in addition to any penalty prescribed by law. (For a list of some offenses for which disciplinary action may be taken and "The Code of Ethics for Government Service," the violation of which may also result in disciplinary action, see Appendixes A and B of this Part).

(b) The type of disciplinary action to be taken must be determined in relation to the specific violation. Those responsible for recommending and for taking disciplinary action must apply judgment to each case, taking into account the general objectives of meeting any requirements of law, deterring similar offenses by the employee and other employees, and maintaining high standards of employee conduct and public confidence. Some types of disciplinary action which may be considered are:

(1) Admonishment
(2) Written reprimand
(3) Reassignment
(4) Suspension
(5) Demotion
(6) Removal

(c) Suspension, demotion, and removal are adverse actions; and when such actions are taken, applicable laws, regulations, and policies must be followed.

[46 FR 7369, Jan. 23, 1981, as amended at 53 FR 4409, Feb. 16, 1988]

Subpart M—Reporting Violations

§ 73.735–1301 Responsibility for reporting possible criminal violations.

An employee who has information which he or she reasonably believes indicates a possible offense against the

United States by an employee of the Department, or any other individual working on behalf of the Department, shall immediately report such information to his or her supervisor, any management official, or directly to the Office of the Inspector General. Offenses covered by the preceding sentence include, but are not limited to, bribery, fraud, perjury, conflict of interest, misuse of funds, equipment, or facilities, and other conduct by a government officer or employee, grantee, contractor or other person which is prohibited by title 18 of the United States Code. Employees and supervisors should refer to chapter 5-10 of the Department's General Administration Manual for procedures regarding the reporting and handling of such information.

§ 73.735-1302 Responsibility for reporting allegations of misconduct.

An employee who has information which he or she reasonably believes indicates the existence of an activity constituting (a) a possible violation of a rule or regulation of the Department; or (b) mismanagement, a gross waste of funds, or abuse of authority; or (c) a substantial and specific danger to the public health and safety, shall immediately report such information to his or her supervisor, any management official of the Department, or directly to the Office of the Inspector General. Employees and supervisors should refer to chapter 5-10 of the Department's General Administration Manual for procedures regarding the reporting and handling of such information. This subsection does not cover employee grievances, equal employment opportunity complaints, classification appeals, or other matters for which a formal government-wide review system has been established by the Federal government.

§ 73.735-1303 Prohibition of reprisals.

(a) Any employee who has authority to take, direct others to take, recommend, or approve any personnel action, shall not, with respect to such authority, take or threaten to take any action against any employee as a reprisal for making a complaint or providing any information pursuant to §§ 73.735-1301 and 73.735-1302. If the complaint was made or the information was disclosed with the knowledge that it was false, or with willful disregard of its truth or falsity, any personnel action taken against the employee based on those reasons would not constitute a reprisal action.

(b) An employee who believes that he or she has been threatened with a personnel action, any other action, or harassment or has been harmed by any action as a reprisal for having made a complaint or providing information pursuant to § 73.735-1301 or § 73.735-1302 may request the Office of the Inspector General to review his or her allegations. Whenever the Inspector General has reason to believe that the allegations may be true, he or she will refer the matter to the Assistant Secretary for Personnel Administration for appropriate action. The Assistant Secretary for Personnel Administration may order a stay of any personnel action if he or she determines that there are reasonable grounds to believe that the personnel action is being taken as a reprisal for making a complaint or providing information pursuant to § 73.735-1301 or § 73.735-1302.

§ 73.735-1304 Referral of matters arising under the standards of this part.

(a) The Department Ethics Counselor may refer to the Inspector General for investigation and/or further action any matter arising under the standards of this part.

(b) The Department Ethics Counselor may refer to the Office of Government Ethics, or the Inspector General may refer to the Department of Justice, suspected violations of the criminal laws regarding employee standards of conduct and conflicts of interest.

Subpart N—Conduct and Responsibilities of Former Employees

§ 73.735-1401 Prohibitions against post-employment conflicts of interest.

(a) The purpose of criminal prohibition in 18 U.S.C. 207 is to prevent the unfair use of inside knowledge or influence that results from Federal service. 18 U.S.C. 207 generally prohibits a former employee from acting as another person's representative to the Government in particular matters involving a specific party or parties in which the employee had been involved while in Federal service. This prohibition does not require a former employee to decline employment with any organization regardless of his or her dealings with that organization while employed by the Government. It applies solely to activities, not the mere existence of an employment arrangement.

(b) The Office of Government Ethics, Office of Personnel Management, has issued Government-wide regulations covering post-employment conflict of interest (5 CFR Part 737). Those regulations are incorporated herein by reference, and they are available for review in personnel offices throughout the Department.

APPENDIX A TO PART 73—LIST OF SOME OFFENSES FOR WHICH DISCIPLINARY ACTION MAY BE TAKEN

Following is a list of some offenses for which disciplinary action may be taken under this Part. When a statute applies specifically to a particular offense, either wholly or in part, the statute is cited. Neither the list of offenses nor the statutory citations are all inclusive. The "Code of Ethics for Government Service" is not cited because of its general applicability but is published in its entirety in Appendix B.

A. *Concerning Efficiency of Operations in General.* 1. Engaging in wasteful actions or behavior in the performance of assigned duties; conducting non-Government business during official work hours; or participating in a strike (18 U.S.C. 1918), work stoppage, slowdown, sickout, or other similar action.

2. Absence without leave, failure to adhere to the rules and regulations for requesting and obtaining leave, or improper use of sick leave.

3. Deliberate insubordination or refusal to carry out lawful orders or assignments given.

4. Disruptive behavior, such as:

a. Inflicting or threatening or attempting to inflict bodily injury on another (except for necessary defense of self or others) while on the job or on Federal premises.

b. Discourtesy, disreputable conduct, or use of insulting, abusive or obscene language to or about other individuals while on the job.

5. Sexual harassment of employees or members of the public.

6. Failure to observe precautions for safety, such as failure to use safety equipment when it is provided or ignoring signs, posted rules or regulations, or written or verbal safety instructions.

7. Unauthorized use, possession, or distribution of alcoholic beverages (5 U.S.C. 7352) or controlled substances (e.g., hallucinogens, such as LSD; stimulants, such as cocaine and amphetamines; sedatives, such as barbiturates; narcotics and other drugs or substances, such as hashish and other cannabis substances).

8. Unauthorized gambling; or canvassing, soliciting, or peddling on Government premises.

9. Failure to carry or show proper identification or credentials as required by competent authority; misuse of identification cards or investigative or identification credentials or badges.

10. Failure to disclose (i.e., report) information, when such disclosure is not specifically prohibited by law or Executive Order, that involves (a) violation of law, rule, or regulation, (b) mismanagement or gross waste of funds or abuse of authority, or (c) posing a substantial and specific danger to public health or safety; failure to cooperate in an official Department inquiry.

11. Failure to pay just debts, including taxes to and loans from governmental sources.

12. Deceit or interference in a Civil Service examination (18 U.S.C. 1917) or in connection with a Government personnel action.

13. Fraud or false statements in a Government matter. (18 U.S.C. 1001 through 1003.)

14. Supervisory failure to initiate disciplinary or corrective action when the facts are known and disciplinary or corrective action is warranted.

15. Employment of a member of an organization that advocates the overthrow of our constitutional form of government. (5 U.S.C. 7311; 50 U.S.C. 784.)

B. *Concerning Government Funds, Property, Documents, and Records.* 1. Actual or attempted embezzlement or theft of Government or personal money or property either directly or through use of Government documents, automated equipment, or other means; actual or attempted embezzlement or theft of the money or property of another person in the possession of an employee by reason of his or her employment. (18 U.S.C. 641 and 654.)

2. Failure to account for public money. (18 U.S.C. 643.)

3. Deliberate falsifying of official time and attendance records; improper use of official travel or forging, counterfeiting, or other-

wise falsifying official Government travel records or documents. (18 U.S.C. 508.)

4. False record entries or false reports of money or securities. (18 U.S.C. 2073.)

5. Loss or misuse of or damage to Government property or endangering persons or Government property through carelessness or by willful malicious conduct.

6. Mutilating, destroying, or concealing public records. (18 U.S.C. 2071.)

7. Misuse of penalty (postal) privilege. (18 U.S.C. 1719.)

8. Failure to safeguard administratively confidential, financial, and trade secrets information.

9. Unauthorized use of documents presented or used to procure the payment of money from or by the Government. (18 U.S.C. 285.)

10. Unauthorized use of a Government vehicle; serious or repeated violations of traffic regulations while driving a Government vehicle or a vehicle rented or leased for official Government purposes; reckless driving or improper operation of any Government owned, rented, or leased motor vehicle. (31 U.S.C. 1349[b].)

11. Violations of the Privacy Act, including:

a. Willful prohibited disclosure of individually identifiable information in violation of 5 U.S.C. 552a.

b. Willfully maintaining a system of records without meeting the notice requirements of the Privacy Act as required by 5 U.S.C. 552a.

12. Violation of regulations concerning the release of classified information, confidential, or security and investigative information. (18 U.S.C. 798 and 1905; 21 U.S.C. 331j; and 50 U.S.C. 783.)

C. *Concerning Conflicts of Interest and Related Unethical Conduct*: 1. Violations of 18 U.S.C. Chapter 11: Bribery, Graft, and Conflicts of Interest, including:

a. Having a direct or indirect financial interest (includes employee ownership of stocks, bonds, or partnership interests in an entity or employment of the employee, his or her spouse, or dependent child) that conflicts with one's Government duties because such entity is either regulated by, has or seeks to do business with the agency, or has any other particular matter with or pending before the agency that may give rise to either an actual conflict or the appearance thereof. (18 U.S.C. 208.)

b. Bribery of a public official; soliciting or accepting directly or indirectly anything of monetary value, including gifts, gratuities, favors, entertainment, or loans either as compensation for governmental services or from individuals who are seeking contractual or other business or financial relations with the Department, are conducting operations or activities that are regulated by the Department, or have interests that may be substantially affected by the performance or nonperformance of the employee's official duties; receiving salary or any contribution to or supplementation of salary from a private source as compensation for services for the Government. (18 U.S.C. 201 and 209.)

c. Acting as the agent of a foreign principal registered under the Foreign Agents Registration Act. (18 U.S.C. 219.)

2. Engaging, directly or indirectly, in a financial transaction as a result of or primarily relying on information that is obtained through one's official duties and would not be available were the employee not an employee of the Federal Government.

3. Soliciting a contribution from another employee for a gift to an official superior, making a donation as a gift to an official superior, or accepting a gift from an employee receiving less pay than oneself. (5 U.S.C. 7351.)

4. Engaging, without required permission, in outside activities that result in or create the appearance of a conflict of interest.

5. Teaching, lecturing, or writing that depends on specific information obtained as a result of one's Government employment when that information is not otherwise available to the public.

6. Failure to obtain required clearance of an official speech or article.

7. Lobbying with appropriated funds. (18 U.S.C. 1913.)

8. Representation before a Federal agency (other than in the proper discharge of one's official duties) as an agent or attorney in a claim against the United States (or receiving any gratuity or share in any such claim in considertion for assistance given) or as an agent or attorney for anyone before any department, agency, court, or otherwise in connection with any proceeding, application, request for a ruling, or claim on any other particular matter in which the United States is a party or has a direct and substantial interest. (18 U.S.C. 205.) (Note: This section notwithstanding, an employee may, if not inconsistent with the performance of his or her official duties, act without compensation as an agent or attorney for another person who is the subject of any disciplinary or other administrative proceeding or as an agent or attorney for one's parent, spouse, child, or any person or estate for whom or which he or she serves as personal fiduciary except in those matters in which the employee has participated personally and substantially.)

D. *Concerning Prohibited Political and Election Activities*. 1. Activities prohibited by 5 U.S.C. Chapter 73, Subchapter III, including:

a. Section 7323, "Political contributions prohibition."

b. Section 7324, "Influencing elections; taking part in political campaigns; prohibitions; exceptions."

2. Activities prohibited by 18 U.S.C. Chapter 29, including:

a. Section 594, "Intimidation of voters."

b. Section 597, "Expenditures to influence voting."

c. Section 598, "Coercion by means of relief appropriations."

d. Section 600, "Promise of employment or other benefit for political activity."

e. Section 601, "Deprivation of employment or other benefit for political contribution."

f. Section 602, "Solicitation of political contributions."

g. Section 604, "Solicitation from persons on relief."

h. Section 606, "Intimidation to secure political contributions."

E. *Concerning Prohibited Personnel Practices.* 1. Commission of a prohibited personnel practice (as defined in 5 U.S.C. 2302[b] [1-11]); that is, any employee who has authority to take, direct others to take, recommend, or approve any personnel action, shall not, with respect to such authority, commit any of the following practices:

a. Discriminate for or against any employee or applicant for employment on the basis of race, color, religion, sex, national origin, age, handicapping condition, marital status, or political affiliation.

b. Solicit or consider any recommendation or statement, oral or written, with respect to any individual who requests or is under consideration for any personnel action unless such recommendation or statement is based on the personal knowledge or records of the person furnishing it and consists of (1) an evaluation of the work performance ability, aptitude, or general qualifications of such individual or (2) an evaluation of the character, loyalty, or suitability of such individual.

c. Coerce the political activity of any person (including the providing of any political contribution or service) or take any action against any employee or applicant for employment as a reprisal for the refusal of any person to engage in such political activity.

d. Deceive or willfully obstruct any person with respect to such person's right to compete for employment.

e. Influence any person to withdraw from competition for any position for the purpose of improving or injuring the prospects of any other person for employment.

f. Grant any preference or advantage not authorized by law, rule, or regulation to any employee or applicant for employment (including defining the scope or manner of competition or the requirements for any position) for the purpose of improving or injuring the prospects of any particular person for employment.

g. Appoint, employ, promote, advance, or advocate for appointment, employment, promotion, or advancement, in or to a civilian position any individual who is a relative (as defined in 5 U.S.C. 3110) when the civilian position is in the Department or under his or her jurisdiction or control.

h. Take or fail to take a personnel action with respect to any employee or applicant for employment as a reprisal for the lawful disclosure of information.

i. Take or fail to take any personnel action against an employee or applicant for employment as a reprisal for the exercise of any appeal right granted by any law, rule, or regulation (including HHS Instructions and issuances).

j. Discriminate for or against any employee or applicant for employment on the basis of conduct that does not adversely affect the performance of the employee or applicant or the performance of others (except criminal conviction in determining suitability or fitness).

k. Take or fail to take any personnel action when the taking of or failure to take such action violates any law, rule, or regulation implementing, or directly concerning the merit system principles (as set forth in 5 U.S.C. 2301).

[53 FR 4410, Feb. 16, 1988]

APPENDIX B TO PART 73—CODE OF ETHICS FOR GOVERNMENT SERVICE

Any person in Government service should:

I. Put loyalty to the highest moral principles and to country above loyalty to persons, party, or Government department.

II. Uphold the Constitution, laws, and regulations of the United States and all governments therein and never be a party to their evasion.

III. Give a full day's labor for a full day's pay, giving earnest effort and best thought to the performance of duties.

IV. Seek to find and employ more efficient and economical ways of getting tasks accomplished.

V. Never discriminate unfairly by the dispensing of special favors or privileges to anyone, whether for remuneration or not; and never accept, for himself or herself or family members, favors or benefits under circumstances which might be construed by reasonable persons as influencing the performance of governmental duties.

VI. Make no private promises of any kind binding upon the duties of office, since a Government employee has no private word which can be binding on public duty.

VII. Engage in no business with the Government, either directly or indirectly, which is inconsistent with the conscientious performance of governmental duties.

VIII. Never use any information gained confidentially in the performance of governmental duties as a means of making private profit.

IX. Expose corruption wherever discovered.

X. Uphold these principles, ever conscious that public office is a public trust.

[53 FR 4410, Feb. 16, 1988]

PART 73a—STANDARDS OF CONDUCT: FOOD AND DRUG ADMINISTRATION SUPPLEMENT

Subpart A—General Provisions

Sec.
73a.735-101 Principles and purpose.
73a.735-103 Responsibilities.
73a.735-104 Advice and guidance.

Subpart B—Miscellaneous Provisions

73a.735-201 Control activity employees formerly associated with organizations subject to FDA regulation.

Subpart C—[Reserved]

Subpart D—Outside Employment

73a.735-401 General provisions.

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73a.735-501 General provisions.
73a.735-502 Employees in regulatory activities.
73a.735-504 Exceptions.

Subparts F—I [Reserved]

Subpart J—Statements of Employment and Financial Interests

73a.735-1004 Submission and review of statements.

AUTHORITY: 45 CFR 73.735-105.

SOURCE: 43 FR 7619, Feb. 24, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 73a.735-101 Principles and purpose.

(a) To assure that the business of the Food and Drug Administration (FDA) is conducted effectively, objectively, and without improper influence or appearance thereof, all employees must be persons of integrity and observe the highest standards of conduct. Because of FDA's special regulatory responsibilities to the consumer and industry, its employees must be especially alert to avoid any real or appearance of conflict of their private interests with their public duties. Their actions must be unquestionable and free from suspicion of partiality, favoritism, or any hint of conflicting interests. This supplement recognizes FDA's public obligation to set reasonable and fair safeguards for the prevention of employee conflicts of interest. It is necessary to meet FDA's regulatory responsibilities and to otherwise assure full protection of the public confidence in the integrity of its employees.

(b) Since FDA is a unique consumer protection and regulatory agency within the Department, the DHHS Standards of Conduct need further supplementation to reflect this role. Therefore, for purposes of implementing the DHHS Standards of Conduct regulations within the FDA, this supplement provides interpretive definitions and additional requirements. As further guidance to its employees and supervisory officials, FDA will issue internal procedural instructions in accordance with this supplement.

§ 73a.735-103 Responsibilities.

(a) A "control activity" employee shall be personally responsible for assuring that he does not hold an interest in any organization whose FDA-regulated activities constitute more than an insignificant part of its business as defined in § 73a.735-502(b)(2). The Associate Commissioner for Administration (or his designee) is available to assist such employees in obtaining corporate data necessary to make such a determination.

(b) Other employees are similarly responsible for observing the financial interest retention requirements in §§ 73a.735-501(b) and 73a.735-502(a)(2).

§ 73a.735-104 Advice and guidance.

(a) The Associate Commissioner for Administration (or his designee) shall provide day-to-day guidance and assistance to employees and supervisors on matters covered by regulations in Part 73 and this part of this chapter.

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(b) The FDA Conflict of Interest Review Board shall review and make recommendations to the Commissioner on requests for exceptions to conflict of interest policies and procedures in regulations in this part and Part 73 of this chapter.

Subpart B—Miscellaneous Provisions

§ 73a.735-201 Control activity employees formerly associated with organizations subject to FDA regulation.

(a) For a period of 1 year after FDA appointment, or appointment to the Food and Drug Division, Office of the General Counsel, a control activity employee who was employed in a regulated organization within 1 year before FDA employment shall not participate in any regulatory action before FDA that involves the former employer organization. Exceptions may be authorized only under paragraph (e) of this section.

(b) A control activity employee who was previously employed in a regulated organization shall not participate in any regulatory action before FDA in which the employee had participated personally and substantially in behalf of the former employer organization, e.g., drug investigations/applications, food additive petitions, matters dealing with compliance in areas of radiation-producing products or medical devices. Exceptions may be authorized only under paragraph (e) of this section.

(c) Employment in a regulated organization includes contractual relationships, e.g., attorneys who may have represented an FDA-regulated firm or industry or an association of such firms and individuals who may have served a firm, industry or association in a consultant capacity.

(d) Within 30 days after assignment to a control activity position, an employee shall submit to his supervisor detailed information concerning former industry employers, and dates and substance of involvement in such regulatory matters as may be subject to the prohibition in paragraph (b) of this action.

(e) The Commissioner may grant individual exceptions to paragraphs (a) and (b) of this section whenever he determines that strict application would not be in the best interests of the United States. A memorandum of any exception granted shall be filed for public inspection in the Public Records and Documents Center, Food and Drug Administration, Room 4-68, 5600 Fishers Lane, Rockville, Md. 20857, within 10 days after the Commissioner's decision. The memorandum shall include the employee's name, title, grade, summary of official duties, prior pertinent industry involvement, a brief description of the specific regulatory action in which the employee has been permitted to participate, and a statement explaining why such strict application of the subpart would not be in the best interests of the United States.

Subpart C—[Reserved]

Subpart D—Outside Employment

§ 73a.735-401 General provisions.

(a) Employees of the Food and Drug Administration shall obtain advance approval for all outside employment, whether paid or unpaid. Employment, as used in this section, does not include:

(1) Memberships in charitable, religious, social, fraternal, recreational, public service, civic, or similar nonbusiness organizations.

(2) Memberships in professional organizations. (Officeholding, however, requires advance approval.)

(3) Performance of duties in the Armed Forces Reserve or National Guard.

(b) Control activity employees (defined in § 73a.735-502) will not generally be granted approval to:

(1) Manage or direct an organization whose activities are subject to FDA regulation, or

(2) Be employed in an organization whose business activities are subject to FDA regulation unless:

(i) The regulated activities of the organization are an insignificant part of its total operations, i.e., the regulated products of the organization constitute no more than 10 percent of its annual gross sales, and

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(ii) The outside employment is in nonregulated activities of the organization.

(c) All other employees will generally be granted approval to engage in outside employment which is compatible with the full performance of their FDA duties and responsibilities and which will not give rise to a real or apparent conflict of interest. Permissible employment includes but is not limited to:

(1) Employment where the sale of FDA-regulated products is incidential to the purpose of the establishment, e.g., hotels, theaters, bowling alleys, and sports arenas.

(2) Sales and clerical occupations relating to regulated products, e.g., supermarkets, drugstores, department stores, liquor stores.

(3) Trade, industrial, and service occupations relating to regulated products, e.g., gasoline service station attendant, line production or assembly work, cook, waiter, waitress, hospital attendant, snack bar vendor, warehouseman.

(d) All employees will generally be granted approval to engage in paid or unpaid outside employment which contributes to their technical or professional development, e.g.,

(1) Medical, dental, and veterinary practices.

(2) Pharmacy practice after meeting the following conditions which will serve to protect against possible conflicts or apparent conflicts of interest and to avoid other problems resulting in embarrassment to the employee or FDA:

(i) The primary purpose of the part-time employment is to contribute to the overall professional development of the employee and generally enhance his capability to better perform his current FDA duties.

(ii) The part-time duties will be confined generally to dispensing Rx drugs and related professional pharmacy duties.

(iii) The employee will avoid unrelated nonprofessional duties such as supervision or management of store operations, contractual or purchasing responsibilities (except normal "out-of-stock" requisitioning) and repacking and relabeling of bulk items.

(iv) The employee will demonstrate a high degree of discretion and judgment in his contacts with customers and representatives of regulated industry and competitor firms so as to avoid giving the impression that:

(*a*) His part-time actions, recommendations, opinions, or remarks are official points of view;

(*b*) He is using his FDA position for private gain by oral misrepresentations and false claims of the company's products;

(*c*) He is making a Government decision outside official channels, e.g., to customers, prescribing physicians, buyers, distributors;

(*d*) He or other FDA representatives will give preferential treatment to any regulated organization or representatives of such organizations, or that FDA employees have not exercised complete independence or impartiality in carrying out their regulatory and consumer protection responsibilities; or

(*e*) His part-time work is creating an adverse effect on the image of FDA or discrediting the integrity of official FDA regulatory decisions.

Subpart E—Financial Interests

§ 73a.735-501 General provisions.

(a) No restrictions are placed on ownership of diversified mutual funds.

(b) An FDA employee, other than a control activity employee (defined in § 73a.735-502), may have financial interests:

(1) In an organization whose FDA-regulated activities are an insignificant part of its total operations, i.e. no more than 10 percent of the organization's annual gross sales are in products regulated by FDA; or

(2) In an organization whose FDA-regulated business activities are a significant part of its total business operations: *Provided*, That:

(i) The holding is less than $5,000 (value or cost at time of initial reporting),

(ii) The holding represents less than 1 percent of the total outstanding stock shares of that organization, and

(iii) No more than 50 percent of the employee's total investment value is concentrated in organizations whose FDA-regulated business activities are a significant part of their business operations.

(c) Notwithstanding the provisions of this part permitting employees to hold financial interests in organizations subject to FDA regulation, an employee holding such an interest shall not participate in an official matter whose outcome would have a direct and predictable effect on his financial interest. However, this prohibition is not applicable to:

(1) Diversified mutual funds, which are exempted from 18 U.S.C. 208 by § 73.735-501(a) of this chapter.

(2) Financial interests for which the Commissioner has in advance granted a written exception on the ground that the public interest would be served if a particular employee is allowed to participate in an official matter whose outcome may have a direct and predictable effect on the employee's financial interest. Such exemptions will be granted only in exceptional circumstances. Any determination to authorize such exceptions shall be made in accordance with 18 U.S.C. 208(b)(1) and documented for public inspection in accordance with § 73a.735-504.

§ 73a.735-502 Employees in regulatory activities.

(a) An employee in regulatory activities ("control activity" employee) may hold financial interests in an FDA-regulated organization only if either of the following conditions are met:

(1) The regulated activities of the organization are an "insignificant" part of its total business operations, or

(2) Written approval for an individual exception is granted by the Commissioner in accordance with § 73a.735-504; however, such approval will not be considered unless all of the following conditions are met:

(i) Retention of the financial interest does not give rise to an actual conflict of interest;

(ii) Acquisition of the financial interest occurred by marriage or inheritance, or the interest was held prior to an FDA reorganization, change in regulations, or similar circumstances beyond the control of the employee that resulted in the interest becoming prohibited;

(iii) No direct relationship exists between the employee's official duties and the regulated activities of the organization in which the financial interest is held;

(iv) The employee occupies a position below that of Bureau/Deputy Bureau Director (or Assistant/Deputy General Counsel, Food and Drug Division, Office of the General Counsel); and

(v) The employee agrees to refrain from engaging, either directly or indirectly, in transactions that are designed to increase the value of his "excepted" financial interest.

(b) To administer provisions within this part, the following interpretations apply:

(1) A "control activity" employee ("control activity" positions are identified in Appendix C to Part 73 of this chapter), means one who:

(i) Occupies an FDA position classified at GS-11 or above, or PHS Commissioned Officer 0-3 or above, or equivalent;

(ii) Occupies an FDA position below GS-11 with duties of a nature that the employee could in the discharge of his official duties and responsibilities cause an economic advantage for or impose a handicap on a non-Federal enterprise (includes investigators, inspectors, regulatory analysts);

(iii) Occupies a position at GS-11 or above in the Office of the Assistant General Counsel, Food and Drug Division.

(2) "Insignificant" (part of an organization's total business operations) means that the FDA-regulated products constitute no more than 10 percent of the organization's annual gross sales.

§ 73a.735-504 Exceptions.

(a) A control activity employee who can satisfy all of the conditions specified in § 73a.735-502(a)(2) may submit a request to retain a prohibited financial interest. Any such request must be submitted no later than 30 days after the event that results in the employee holding the prohibited financial interest. Such requests for exception should be forwarded in writing through supervisory channels to the Associate Commissioner for Administration for review by the FDA Conflict of Interest Review Board and subsequent recommendation to the Commissioner. All decisions on requests for exceptions shall be in writing and a copy furnished to the employee involved.

(b) A memorandum of each approved exception shall be filed in the Public Records and Documents Center for public inspection. Such public disclosure shall be made within 10 days after the Commissioner's decision. The following is an example of the format of such memorandum (in a hypothetical employee situation):

(1) Employee: Joe Doe.

(2) Title: Research Chemist.

(3) Grade/Salary: GS-14.

(4) Organization: Bureau of Biologics, Food and Drug Administration, Bethesda, Md.

(5) Date of employee's request for exception: ——.

(6) Date of Commissioner's approval: ——.

(7) Basis for exception: Employee owns financial interest in the ABC Foods Corporation, and permanent retention is normally prohibited under FDA/HHS conflict of interest regulations for such an employee. The employee, however, acquired this financial interest prior to his reassignment to FDA on ——, which was part of a major Department reorganization transferring certain functions from NIH to the FDA (i.e., FDA's Bureau of Biologics). At the time of acquisition and immediately prior to the reorganization, the employee's financial interest was allowable under Department regulations. The employee's official duties are fully confined to the matters under the jurisdiction of the Bureau of Biologics, and his official duties do not involve any contact with the food industry. The Commissioner has determined that an exception is warranted under the following criteria:

(i) Acquisition occurred prior to Department reorganization;

(ii) Financial interest retention will not give rise to an actual conflict of interest situation;

(iii) There is no direct relationship between the employee's official duties and the regulated activities of ABC Foods;

(iv) The employee occupies a position below that of Bureau or Deputy Bureau Director (or equivalent position in the Office of the Commissioner); and

(v) The employee agrees to refrain from engaging in any direct or indirect transactions that are designed to increase the value/shares of the "excepted" ABC Foods interests.

This exception is considered equitable to the employee involved, and retention of the ABC Foods interest will not in any way impair the interests of the Government or of the public.

(c) In interpreting the requirement of § 73a.735-502(a)(2)(v), events not involving employee discretion (e.g., accepting dividends in the form of cash or additional shares) do not constitute transactions designed to increase the value/shares of an "excepted" financial interest. A transaction involving discretion, e.g., exercise of stock options, may be made only if proposed to the Associate Commissioner for Administration and approved by the Conflict of Interest Review Board as an amendment to the original exception. A memorandum recording such approval shall be made public in accordance with paragraph (b) of this section.

(d) An employee may temporarily retain a prohibited financial interest pending review of a written request for an exception submitted in accordance with this section.

(e) Except as provided in § 73a.735-501(c), no employee may participate in an official matter whose outcome will have a direct and predictable effect on a financial interest held by him. This prohibition applies to official matters handled before and after approval of an exception under this section.

Subparts F—I [Reserved]

Subpart J—Statements of Employment and Financial Interests

§ 73a.735-1004 Submission and review of statements.

(a) Employees occupying control activity positions shall file Form HHS-473 "Confidential Statement of Employment and Financial Interests" with the Associate Commissioner for Administration within 30 days after entrance in this category and annually thereafter as of June 30, or such other dates as the Secretary, with the concurrence of the Civil Service Commission, may approve. Prior to the due date, the Associate Commissioner for Administration shall advise "control activity" employees of the annual filing requirement through normal administrative channels. The annual reporting requirement shall commence as of June 30, 1977.

(b) The Associate Commissioner for Administration (or his designee) shall serve as the principal reviewing official for Outside Activity Forms, HHS-520 and 521, and shall make final determinations on matters arising from activities reported on Form HHS-473.

PART 73b—DEBARMENT OR SUSPENSION OF FORMER EMPLOYEES

Sec.
73b.1 Scope.
73b.2 Rules and regulations.
73b.3 Reports of violations.
73b.4 Proceedings.
73b.5 Hearings.

AUTHORITY: 18 U.S.C. 207(j).

SOURCE: 47 FR 17505, Apr. 23, 1982, unless otherwised noted.

§ 73b.1 Scope.

This part contains rules governing debarment or disqualification action against a former officer or employee of the Department, including former and retired officers of the commissioned corps of the Public Health Service, because of violation of the post-employment restrictions of the conflict of interest laws and regulations.

§ 73b.2 Rules and regulations.

This part will be applied in conformance with the standards established by the Office of Government Ethics in its regulations, 5 CFR Part 737, and interpretations thereof. Former officers and employees of the Department may request advice and assistance in compliance with those regulations from the Assistant General Counsel, Business and Administrative Law Division, Department of Health and Human Services.

§ 73b.3 Reports of violations.

(a) If an officer or employee of the Department has reason to believe that a former officer or employee of the Department has violated any provision of 18 U.S.C. 207 (a), (b) or (c) or if any such officer or employee receives information to that effect, he/she shall promptly make a written report thereof which shall be forwarded to the Inspector General. If any other person has information of such violations, he/she may make a report thereof to the Inspector General or to any officer or employee of the Department.

(b) The Inspector General shall coordinate proceedings under this part with the Department of Justice in cases where it appears criminal prosecution is warranted.

§ 73b.4 Proceedings.

(a) Upon a determination by the Assistant General Counsel, Business and Administrative Law Division, or his/her designee, after investigation by the Inspector General, that there is reasonable cause to believe that a former officer or employee, including a former special Government employee, of the Department of Health and Human Services (former departmental employee) has violated 18 US.C. 207 (a), (b) or (c), the Assistant General Counsel, or his/her designee, shall cause a copy of written charges of the violation(s) to be served upon such individual, either personally or by registered mail. The charges shall be accompanied by a notice to the former departmental employee to show cause within a specified time of not less than 30 days after receipt of the notice why he/she should not be prohibited from engaging in representational activities in relation to matters pending in the Department, as authorized by 18 U.S.C. 207(j), or subjected to other appropriate debarment or disqualification action under that statute. The notice to show cause shall include:

(1) A statement of allegations, and their bases, sufficiently detailed to enable the former departmental employee to prepare an adequate defense;

(2) Notification of the right to a hearing, and that failure to answer shall constitute a waiver of defense; and

(3) An explanation of the method by which a hearing may be requested.

(b) If a former departmental employee who submits an answer to the notice to show cause does not request a hearing or if the Assistant General Counsel does not receive an answer within the time prescribed by the notice, the Assistant General Counsel shall forward the record, including the report(s) of investigation, to the Assistant Secretary for Personnel Administration (Assistant Secretary). In the case of a failure to answer, such failure shall constitute a waiver of defense.

(c) Upon receipt of a former departmental employee's request for a hearing, the Assistant General Counsel shall notify him/her of the time and place thereof, giving due regard both to such person's need for an adequate period to prepare a suitable defense and an expeditious resolution of allegations that may be damaging to his or her reputation.

(d) The presiding officer at the hearing and any related proceedings shall be a federal administrative law judge. He/she shall insure that the former departmental employee has the following rights:

(1) To self-representation or representation by counsel,

(2) To introduce and examine witnesses and submit physical evidence,

(3) To confront and cross-examine adverse witnesses,

(4) To present oral argument, and

(5) To a transcript or recording of the proceedings, upon request.

(e) The Assistant General Counsel shall designate one or more officers or employees of the Department to present the evidence against the former departmental employee and perform other functions incident to the proceedings.

(f) A decision adverse to the former departmental employee must be sustained by substantial evidence that he/she violated 18 U.S.C. 207 (a), (b) or (c). If a judgment of conviction has been entered by a Federal district court against the former departmental employee for violation of 18 U.S.C. 207 (a), (b) or (c), regardless of whether the judgment is based upon a verdict or a plea of guilty, such judgment of conviction shall be conclusive evidence of a violation of 18 U.S.C. 207 (a), (b) or (c), unless and until the judgment is vacated or reversed on appeal.

(g) The administrative law judge shall issue an initial decision based exclusively on the transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, and shall set forth in the decision findings and conclusions, supported by reasons, on the material issues of fact and law presented on the record.

(h) Within 30 days after issuance of the initial decision, either party may appeal in writing to the Assistant Secretary who in that event shall issue the final decision based on the record of the proceedings or those portions thereof cited by the parties to limit the issues. If the final decision modifies or reverses the initial decision, the Assistant Secretary shall specify the findings of fact and conclusions of law that vary from those of the presiding officer.

(i) If a former departmental employee fails to appeal from an adverse initial decision within the prescribed period of time, the administrative law judge shall forward the record of the proceedings to the Assistant Secretary.

(j) In the case of a former departmental employee who filed an answer to the notice to show cause but did not request a hearing, the Assistant Secretary shall make the final decision on the record submitted to him by the Assistant General Counsel pursuant to paragraph (b) of this section.

(k) In a case where:

(1) The defense has been waived,

(2) The former departmental employee has failed to appeal from an adverse initial decision, or

(3) The Assistant Secretary has issued a final decision that the former departmental employee violated 18 U.S.C. 207 (a), (b) or (c),

The Assistant Secretary may issue an order:

(i) Prohibiting the former departmental employee from making, on behalf of any other person (except the United States), any informal or formal appearance before, or, with the intent to influence, any oral or written communication to, the Department on a pending matter of business for a period not to exceed five years, or

(ii) Prescribing other appropriate debarment or disqualification action, such as limiting the action to a particular organization or organizations within the Department.

(l) An order issued under either paragraph (k)(i) or (k)(ii) of this section shall be supplemented by a directive to officers and employees of the Department not to engage in conduct in relation to the former departmental employee that would contravene such order.

§ 73b.5 Hearings.

(a) Hearings shall be stenographically recorded and transcribed and the testimony of witnesses shall be taken under oath or affirmation. Hearings will be closed unless an open hearing is requested by the respondent, except that if classified information or protected information of third parties is likely to be adduced at the hearing, it will remain closed. If either party to the proceeding fails to appear at the hearing, after due notice thereof has been sent to him/her, he/she shall be deemed to have waived the right to a hearing and the administrative law judge may make a decision on the basis of the record before him/her at that time.

(b) The rules of evidence prevailing in courts of law and equity are not controlling in hearings under this part. However, the administrative law judge shall exclude evidence which is irrelevant, immaterial, or unduly repetitious.

(c) Depositions for use at a hearing may, with the consent of the parties in writing or the written approval of the administrative law judge be taken by either the Assistant General Counsel or the respondent or their duly authorized representatives. Depositions may be taken upon oral or written interrogatories. There shall be at least 10 days written notice to the other party. The requirement of a 10-day written notice may be waived by the parties in writing. When a deposition is taken upon written interrogatories, any cross-examination shall be upon written interrogatories. Copies of such written interrogatories shall be served upon the other party with the notice, and copies of any written cross-interrogation shall be mailed or delivered to the opposing party at least 5 days before the date of taking the depositions, unless the parties mutually agree otherwise. Expenses in the reporting of depositions shall be borne by the party at whose instance the deposition is taken.

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AUTHORITY: 5 U.S.C. 301; sec. 74.62(a) and Appendix J also issued under sec. 7505, Pub. L. 98-502, 98 Stat. 2333 (31 U.S.C. 7505).

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Subpart A—General

§ 74.1 Purpose and scope of this part.

This part establishes uniform requirements for the administration of HHS grants and principles for determining costs applicable to activities assisted by HHS grants.

§ 74.2 Scope of subpart.

This subpart contains general rules pertaining to this Part 74 (definitions, purpose and scope, applicability, and appeals) and procedures for control of deviations from the part.

§ 74.3 Definitions.

As used in this part:

"*Awarding party*" means (1) with respect to a grant, the granting agency, and (2) with respect to a subgrant, the grantee. (See § 74.4(b))

"*Contract*" means (except as used in the definitions for "grant" and "subgrant" in this section and except where qualified by "Federal") a procurement contract under a grant or subgrant, and "*subcontract*" means a procurement subcontract under such a contract.

"*Cost-type contract*" means a contract or subcontract in which the contractor or subcontractor is paid on the basis of the costs it incurs, but the term does not include such subcontracts under a non-cost-type contract or subcontract.

"*Expenditure report*" means: (1) For nonconstruction grants, the "Financial Status Report" (or other equivalent report); (2) for construction grants, the "Outlay Report and Request for Reimbursement for Construction Programs" (or other equivalent report). (See Subpart I of this part.)

"*Federally recognized Indian tribal government*" means the governing body or a governmental agency of any Indian tribe, band, nation, or other organized group or community (including any Native village as defined in section 3 of the Alaska Native Claims Settlement Act, 85 Stat. 688) certified by the Secretary of the Interior as eligible for the special programs and services provided by him through the Bureau of Indian Affairs. However, for policies applicable to tribal government hospitals and institutions of higher education, see § 74.4(c), "Applicability of this part."

"*For-profit*" organization or institution means a corporation or other legal entity which is organized or operated for the profit or benefit of its shareholders or other owners.

"*Government*" means a State or local government or a federally recognized Indian tribal government. However, for policies applicable to government hospitals and institutions of higher education, see § 74.4(c), "Applicability of this part."

"*Grant*" means an award of financial assistance in the form of money, or property in lieu of money, by the Federal Government to an eligible recipient. The term includes such financial assistance when provided by contract, but does not include any Federal procurements subject to the procurement regulations in 41 CFR, nor does it include technical assistance, which provides services instead of money, or other assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct appropriations. Also, the term does not include assistance, such as a fellowship or other lump sum award, which the recipient is not required to account for on an actual cost basis.

"*Grantee*" means the government, nonprofit corporation, or other legal entity to which a grant is awarded and which is accountable to the Federal Government for the use of the funds provided. The grantee is the entire legal entity even if only a particular component of the entity is designated in the award document. For example, a grant award document may name as the grantee an agency of a State, or one school or campus of a university. In these cases, the granting agency usually intends, or actually requires, that the named component assume primary or sole responsibility for administering the grant-assisted project or program. Nevertheless, the naming of a component of a legal entity as the grantee in a grant award document shall not be construed as relieving the whole legal entity from accountability to the Federal Government for the use of the funds provided. (This definition is not intended to affect the eligibility provisions of grant programs in which eligibility is limited to organizations, such as State welfare departments, which may be only components of a legal entity.) The term "*grantee*" does not include any secondary recipients such as subgrantees, contractors, etc., who may receive funds from a grantee pursuant to a grant.

"*Granting agency*" means any organizational component of HHS authorized to award and administer grants.

"*HHS*" means the U.S. Department of Health and Human Services.

"*Local government*" means a local unit of government including specifically a county, municipality, city, town, township, local public authority, school district, special district, intrastate district, council of governments (whether or not incorporated as a nonprofit corporation under State law), "sponsor or sponsoring local organization" of a watershed project (as defined in 7 CFR 620.2, 40 FR 12472, March 19, 1975), any other regional or interestate government entity, or any agency or instrumentality of a local government. However, for policies applicable to government hospitals and institutions of higher education, see § 74.4(c), "Applicability of this part."

"*OMB*" means the Office of Management and Budget within the Executive Office of the President.

"*OPAL*" means the Office of Procurement, Assistance and Logistics, which is an organizational component within the Office of the Secretary, HHS, and reports to the Assistant Secretary for Management and Budget.

"*Recipient*" means grantee or subgrantee. (See § 74.4(b).)

"*State*" means any of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State exclusive of local governments. However, for policies applicable to government hospitals and institutions of higher education, see § 74.4(c), "Applicability of this part."

"*Subgrant*" means an award of financial assistance in the form of money, or property in lieu of money, made under a grant by a grantee to an eligible subgrantee. The term includes financial assistance when provided by contract, but does not include procurements; nor does it include any form of assistance which is excluded from the definition of "*grant*" in this section.

"*Subgrantee*" means the government, nonprofit corporation, or other legal entity to which a subgrant is awarded and which is accountable to the grantee for the use of the funds provided. The subgrantee is the entire legal entity even if only a particular component of the entity is designated in the subgrant award document.

"*Terms of a grant or subgrant*" means all requirements of the grant or subgrant, whether in statute, regulations, the award document or elsewhere.

[45 FR 22576, Apr. 3, 1980, as amended at 47 FR 53013, Nov. 24, 1982]

§ 74.4 Applicability of this part.

(a) *General.* (1) Except where inconsistent with Federal statutes, regulations, or other terms of a grant, this part applies to all HHS grants, other than the block grant programs identified in 45 CFR 96.1. However, unless expressly made applicable by the granting agency, this part shall not apply when the grantee is a Federal agency, foreign government or organization, international organization such as the United Nations, or individual.

(2) For grants which are subject to 45 CFR Part 92, only the following provisions of this part apply:

(i) Section 74.62(a);
(ii) Section 74.173;
(iii) Section 74.174(b);
(iv) Section 74.304;
(v) Section 74.710; and
(vi) Section 74.715.

(b) *Subgrants.* For each substantive provision in this part, either the language of the provision itself or other text in the same subpart will indicate whether the provision affects only grants, only subgrants, or both. Use of the term "recipient" (as defined in § 74.3) in a provision shall be taken as referring equally to grantees and subgrantees. Similarly, use of the term "awarding party", (as defined in § 74.3) shall be taken as referring equally to granting agencies and to grantees awarding subgrants. However, unless expressly made applicable by the granting agency, this part need not be applied by the grantee to a subgrant if the subgrantee is a Federal agency, foreign government or organization, international organization such as the United Nations, or individual.

(c) *Public institutions of higher education and hospitals.* Grants and subgrants to institutions of higher education and hospitals operated by a government shall be subject only to provisions of this subpart that apply to nongovernmental organizations.

(d) *For-profit organizations.* The attention of for-profit organizations is directed to Subpart AA of this part. The special provisions in that subpart for grants and subgrants to those organizations contain exceptions to other portions of this part.

[47 FR 53013, Nov. 24, 1982, as amended at 53 FR 8079, Mar. 11, 1988]

§ 74.5 Appeals.

In accordance with Parts 16 and 75 of this title, grantees may appeal certain postaward administrative decisions made by HHS officials.

§ 74.6 Deviations.

(a) Except as provided in § 74.7, a deviation is any exception to this part not required by Federal statute without allowance of agency discretion. A deviation may be either:

(1) Use of any policy, procedure, form, standard, or grant or subgrant term which is inconsistent with an applicable provision of this part, or

(2) Failure to use any applicable policy, procedure, form, standard, or grant or subgrant term which is required by this part.

(b) In order to maintain uniformity to the greatest extent feasible, deviations shall be kept to a minimum. A deviation, whether proposed by an applicant, a recipient, or an official of the granting agency, may be authorized only when it is necessary to meet programmatic objectives, or to conserve grant funds, or when it is otherwise essential in the public interest.

(c) Except as provided in paragraph (d) of this section, a deviation from this part may be made only when authorized by both:

(1) The head of the granting agency or other officials if designated in or pursuant to formal deviation control procedures established by the agency; and

(2) OPAL.

(d) Deviations from Subpart Q of this part and Appendixes C, D, E, and F to this part in individual cases (i.e., where only a single grant or subgrant is involved) shall not require OPAL approval.

[45 FR 22576, Apr. 3, 1980, as amended at 47 FR 53013, Nov. 24, 1982]

§ 74.7 Special grant or subgrant conditions.

(a) Without regard to the deviation control procedures of § 74.6, special grant conditions more restrictive than those prescribed in this Part 74 may be imposed as needed when the granting agency has determined that the grantee:

(1) Is financially unstable,

(2) Has a history of poor performance, or

(3) Has a management system which does not meet the standards of this part.

(b) When special conditions are imposed under paragraph (a) of this section, the grantee will be notified in writing:

(1) Why the special conditions were imposed and

(2) What corrective action is needed.

Furthermore, in accordance with OMB Circulars A-102 and A-110, OMB and other Federal agencies in a granting relationship with the grantee will be provided copies of the notice to the grantee.

(c) Grantees may apply the provisions of paragraphs (a) and (b) of this section to their subgrantees. Whenever they do so, a copy of the notice to the subgrantee shall be furnished to the granting agency.

Subpart B—Cash Depositories

§ 74.10 Physical segregation and eligibility.

Except as provided in § 74.11, awarding parties shall not impose grant or subgrant terms which:

(a) Require the recipient to use a separate bank account for the deposit of grant or subgrant funds, or

(b) Establish any eligibility requirements for banks or other financial institutions in which recipients deposit grant or subgrant funds.

§ 74.11 Checks-paid basis letter of credit.

A separate bank account shall be used when payments under letter of credit are made on a "checks-paid" basis. A checks-paid basis letter of credit is one under which funds are not drawn until the recipient's checks have been presented to its bank for payment. (See Subpart K for definition of "letter of credit.")

§ 74.12 Minority-owned banks.

Consistent with the national goal of expanding opportunities for minority business enterprises, grantees and subgrantees are encouraged to use minority-owned banks. Upon request, OPAL will furnish a list of minority-owned banks.

[45 FR 22576, Apr. 3, 1980, as amended at 47 FR 53013, Nov. 24, 1982]

Subpart C—Bonding and Insurance

§ 74.15 General.

In administering grants and subgrants, recipients shall observe their regular requirements and practices with respect to bonding and insurance. No additional bonding and insurance requirements, including fidelity bonds, shall be imposed by the terms of the grant or subgrant except as provided in §§ 74.16 through 74.18.

§ 74.16 Construction and facility improvement.

(a) *Scope of this section.* This section covers requirements for bid guarantees, performance bonds, and payments bonds when the recipient will contract for construction or facility improvement (including alterations and renovations of real property) under a grant or subgrant.

(b) *Definitions.* (1) "Bid guarantee" means a firm commitment such as a bid bond, certified check, or other negotiable instrument accompanying a bid as assurance that the bidder will, if its bid is accepted, execute the required contractual documents within the time specified.

(2) "Performance bond" means a bond executed in connection with a contract to secure fulfillment of all the contractor's obligations under the contract.

(3) "Payment bond" means a bond executed in connection with a contract to assure payment as required by law of all persons supplying labor and material in the execution of the work provided for in the contract.

(c) *Bids and contacts of $100,000 or less.* The recipient shall follow its own requirements and practices relating to bid guarantees, performance bonds, and payment bonds.

(d) *Bids and contracts exceeding $100,000.* The recipient may follow its own regular policy and requirements if the HHS granting agency has determined that the Federal Government's interest will be adequately protected. If this determination has not been made, the minimum requirements shall be as follows:

(1) A bid guarantee from each bidder equivalent to 5 percent of the bid price;

(2) A performance bond on the part of the contractor for 100 percent of the contract price; and

(3) A payment bond on the part of the contractor for 100 percent of the contract price.

§ 74.17 Fidelity bonds.

(a) If the grantee is not a government, the granting agency may require it to carry adequate fidelity bond coverage where the absence of coverage for the grant-supported activity is considered as creating an unacceptable risk.

(b) If the subgrantee is not a government, the granting agency or the grantee may require that it carry adequate fidelity bond coverage where the absence of coverage for the subgrant-supported activity is considered as creating an unacceptable risk.

(c) A fidelity bond is a bond indemnifying the recipient against losses resulting from the fraud or lack of integrity, honesty or fidelity of one or more employees, officers or other persons holding a position of trust.

§ 74.18 Source of bonds.

Any bonds required under § 74.16(d)(1) through (3) or 74.17 shall be obtained from companies holding certificates of authority as acceptable sureties (31 CFR Part 223). A list of these companies is published annually by the Department of the Treasury in its Circular 570.

Subpart D—Retention and Access Requirements for Records

§ 74.20 Applicability.

(a) This subpart applies to all financial and programmatic records, supporting documents, statistical records, and other records of recipients, which are:

(1) Required to be maintained by the terms of an HHS grant, or

(2) Otherwise reasonably considered as pertinent to an HHS grant.

(b) This subpart does not apply to the records of contractors and subcontractors under grants and subgrants. For a requirement to place a provision concerning those records in certain kinds of contracts, see Subpart P and Appendices G and H of this part.

[45 FR 37667, June 3, 1980]

§ 74.21 Length of retention period.

(a) Except as provided in paragraphs (b) and (c) of this section, records shall be retained for 3-years from the starting date specified in § 74.22.

(b) If any litigation, claim, negotiation, audit or other action involving the records has been started before the expiration of the 3-year period, the records shall be retained until completion of the action and resolution of all issues which arise from it, or until the end of the regular 3-year period, whichever is later.

(c) In order to avoid duplicate recordkeeping, awarding parties may make special arrangements with recipients to retain any records which are continuously needed for joint use. The awarding party will request transfer of records to its custody when it determines that the records possess long-term retention value. When the records are transferred to or maintained by the awarding party the 3-year retention requirement is not applicable to the recipient.

§ 74.22 Starting date of retention period.

(a) *General.* (1) Where HHS grant support is continued or renewed at annual or other intervals, the retention period for the records of each funding period starts on the day the grantee submits to HHS its single or last expenditure report for that period. However, if HHS grant support is continued or renewed quarterly, the retention period for each year's records starts on the day the grantee submits to HHS its expenditure report for the last quarter of the Federal fiscal year. In all other cases, the retention period starts on the day the grantee submits its final expenditure report to HHS. If an expenditure report has been waived, the retention period starts on the day the report would have been due. "Expenditure report" is defined in § 74.3.

(2) Exceptions to this paragraph are contained in paragraphs (b) through (d) of this section.

(b) *Equipment records.* The retention period for the equipment records required by § 74.140(a) starts from the date of the equipment's disposition (§ 74.139) or replacement (§ 74.138) or transfer at the direction of the awarding party (§ 74.136).

(c) *Records for income transactions after grant or subgrant support.* (1) In some cases an HHS requirement concerning the disposition of program income, as defined in subpart F of this part, will be satisfied by applying the income to costs incurred after expiration or termination of grant or subgrant support for the activity giving rise to the income. In such a case, the retention period for the records pertaining to the costs starts from the end of the recipient's fiscal year in which the costs are incurred.

(2) In some cases, there may be an HHS requirement concerning the disposition of copyright royalties or other program income which is earned after expiration or termination of grant or subgrant support. Where there is such a requirement, the reten-

tion period for the records pertaining to the earning of the income starts from the end of the recipient's fiscal year in which the income is earned. (See Subpart F of this part.)

(d) *Indirect cost rate proposals, cost allocation plans, etc.*—(1) *Applicability.* This paragraph applies to the following types of documents, and their supporting records:

(i) Indirect cost rate computations or proposals;

(ii) Cost allocation plans under Appendix C to this part;

(iii) Hospital patient care rate computations or proposals; and

(iv) Any similar accounting computations of the rate at which a particular group of costs is chargeable (such as computer usage chargeback rates or composite fringe benefit rates).

(2) *If submitted for negotiation.* If the proposal, plan, or other computation is required to be submitted to the Federal Government (or to the grantee) to form the basis for negotiation of the rate, then the 3-year retention period for its supporting records starts from the date of such submission.

(3) *If not submitted for negotiation.* If the proposal, plan, or other computation is not required to be submitted to the Federal Government (or to the grantee) for negotiation purposes, then the 3-year retention period for the proposal, plan, or computation and its supporting records starts from the end of the fiscal year (or other accounting period) covered by the proposal, plan, or other computation.

§ 74.23 Substitution of microfilm.

Copies made by microfilming, photocopying, or similar methods may be substituted for the original records.

§ 74.24 Access to records.

(a) *Records of grantees.* HHS and the Comptroller General of the United States, or any of their authorized representatives, shall have the right of access to any books, documents, papers, or other records of the grantee which are pertinent to the HHS grant, in order to make audit, examination, excerpts, and transcripts.

(b) *Records of subgrantees.* HHS, the Comptroller General of the United States, and the grantee, or any of their authorized representatives, shall have the right of access to any books, documents, papers, or other records of the subgrantee which are pertinent to the HHS grant, in order to make audit, examination, excerpts, and transcripts.

(c) [Reserved]

(d) *Expiration of right of access.* The rights of access in this section shall not be limited to the required retention period but shall last as long as the records are retained.

[45 FR 22576, Apr. 3, 1980, as amended at 45 FR 37667, June 3, 1980]

§ 74.25 Restrictions on public access.

Unless required by Federal statutes, awarding parties may not impose grant or subgrant terms which limit public access to records covered by this subpart except after a determination by the granting agency that the records must be kept confidential and would have been excepted from disclosure under HHS's "Freedom of Information" regulation (Part 5 of this title) if the records had belonged to HHS. This section does not require recipients to permit public access to their records.

[45 FR 22576, Apr. 3, 1980, as amended at 45 FR 37667, June 3, 1980]

Subpart E—Waiver of Single State Agency Requirements

§ 74.30 Policy.

Requests to HHS from Governors, or other duly constituted State authorities, for waiver of single State agency requirements in accordance with section 204 of the Intergovernmental Cooperation Act of 1968 will be given expeditious handling. Whenever possible, such requests will be granted.

Subpart F—Grant-Related Income

§ 74.40 Scope of subpart.

This subpart contains policies and requirements relating to (a) program income and (b) interest and other investment income earned on advances of grant funds.

§ 74.41 Meaning of program income.

(a) Except as explained in paragraphs (b) and (c) of this section, program income means gross income earned by a recipient from activities part or all of the cost of which is either borne as a direct cost by a grant or counted as a direct cost towards meeting a cost sharing or matching requirement of a grant. It includes but is not limited to such income in the form of fees for services performed during the grant or subgrant period, proceeds from sale of tangible personal or real property, usage or rental fees, and patent or copyright royalties. If income meets this definition, it shall be considered program income regardless of the method used to calculate the amount paid to the recipient—whether, for example, by a cost-reimbursement method or fixed price arrangement. Nor will the fact that the income is earned by the recipient from a Federal procurement contract or from a procurement contract under a Federal grant awarded to another party affect the income's classification as program income.

(b) For research grants that are subject to an institutional cost-sharing agreement, income shall be considered program income only if it is earned from an activity part or all of the cost of which is borne as a direct cost by the Federal grant funds. An institutional cost-sharing agreement is one entered into between HHS and a grantee covering all of HHS's research project grants to the grantee in the aggregate.

(c) The following shall not be considered program income:

(1) Revenues raised by a government recipient under its governing powers, such as taxes, special assessments, levies, and fines. (However, the receipt and expenditure of such revenues shall be recorded as a part of grant or subgrant project transactions when such revenues are specifically earmarked for the project in accordance with the terms of the grant or subgrant.)

(2) Tuition and related fees received by an institution of higher education for a regularly offered course taught by an employee performing under a grant or subgrant.

(d) For the purposes of this subpart, program income is divided into several categories. Each category is treated in a separate section of this subpart.

§ 74.42 General program income.

(a) *Definition.* General program income means all program income accruing to a grantee during the period of grant support or to a subgrantee during the period of subgrant support, other than the special categories of such income treated in §§ 74.43 through 74.45.

(b) *Use.* (1) General program income shall be retained by the recipient and used in accordance with one or a combination of the alternatives in paragraphs (c), (d), and (e) of this section, as follows: The alternative in paragraph (c) of this section may always be used by recipients and must be used if neither of the other two alternatives is permitted by the terms of the grant. The alternatives in paragraph (d) or (e) may be used only if expressly permitted by the terms of the grant. In specifying alternatives that may be used, the terms of the grant may distinguish between income earned by the grantee and income earned by subgrantees and between the sources, kinds, or amounts of income.

(2) The terms of a subgrant may restrict the use of general program income earned by the subgrantee to only one or some of the alternatives permitted by the terms of the grant, but the alternative in paragraph (c) of this section shall always be permitted.

(c) *Deduction alternative.* (1) Under this alternative, the income is used for allowable costs of the project or program. If there is a cost-sharing or matching requirement, costs borne by the income may not count toward satisfying that requirement. Therefore, the maximum percentage of Federal participation is applied to the net amount determined by deducting the income from total allowable costs and third-party in-kind contributions. The income shall be used for current costs unless the granting agency authorizes deferral to a later period.

(2) To illustrate this alternative, assume a project in which the grantee incurs $100,000 of allowable costs and

receives no third-party in-kind contributions. If the grantee earns $10,000 in general program income and this alternative applies, that $10,000 must be deducted from the $100,000 before applying the maximum percentage of Federal participation. If that percentage is 90 percent, the most that could be paid to the grantee would therefore be $81,000 (90 percent times $90,000).

(d) *Cost-sharing or matching alternative.* (1) Under this alternative, the income is used for allowable costs of the project or program but, in this case, the costs borne by the income may count toward satisfying a cost-sharing or matching requirement. Therefore, the maximum percentage of Federal participation is applied to total allowable costs and third-party in-kind contributions. The income shall be used for current costs unless the granting agency authorizes deferral to a later period.

(2) To illustrate this alternative, assume the same situation as in paragraph (c)(2) of this section. Under this alternative, the 90 percent maximum pecentage of participation would be applied to the full $100,000, and $90,000 could therefore be paid to the grantee. (It should be noted that if $20,000 of general program income is earned, only $80,000 could be paid, since a grant cannot pay for costs which have been borne by general program income.)

(e) *Additional costs alternative.* Under this alternative, the income is used for costs which are in addition to the allowable costs of the project or program but which nevertheless further the objectives of the Federal statute under which the grant was made. Provided that the costs borne by the income further the broad objectives of that statute, they need not be of a kind that would be permissible as charges to Federal funds.

Examples of purposes for which the income may be used are:

(1) Expanding the project or program.

(2) Continuing the project or program after grant or subgrant support ends.

(3) Supporting other projects or programs that further the broad objectives of the statute.

(4) Obtaining equipment or other assets needed for the project or program or for other activities that further the statute's objectives.

§ 74.43 Program income—proceeds from sale of real property and from sale of equipment and supplies acquired for use.

The following kinds of program income shall be governed by Subpart O of this part:

(a) Proceeds from the sale of real property purchased or constructed under a grant or subgrant.

(b) Proceeds from the sale of equipment and supplies fabricated or purchased under a grant or subgrant and intended primarily for use in the grant- or subgrant-supported project or program rather than for sale or rental.

§ 74.44 Program income—royalties and other income earned from a copyrighted work.

(a) This section applies to royalties, license fees, and other income earned by a recipient from a copyrighted work developed under the grant or subgrant. Income of that kind is covered by this section whether a third party or the recipient itself acts as the publisher, seller, exhibitor, or performer of the copyrighted work. In some cases the recipient incurs costs to earn the income but does not charge these costs to HHS grant funds, to required cost-sharing or matching funds, or to other program income. Costs of that kind may be deducted from the gross income in order to determine how much must be treated as program income.

(b) The terms of the grant govern the disposition of income subject to this section. If the terms do not treat this kind of income, there are no HHS requirements governing the disposition. A grantee is not prohibited from imposing requirements of its own on the disposition of this kind of income which is earned by its subgrantees provided those requirements are in addition to and not inconsistent with any requirements imposed by the terms of the grant.

§ 74.45 Program income—royalties or equivalent income earned from patents or from inventions.

Disposition of royalties or equivalent income earned on patents or inventions arising out of activities assisted by a grant or subgrant shall be governed by determinations made or agreements entered into under HHS's patent regulations. (See Parts 6 and 8 of this title.) If the determination or agreement does not provide for the disposition of the royalties or equivalent income, the disposition shall be in accordance with the recipient's own policies.

§ 74.46 Program income—income after grant or subgrant support not otherwise treated.

(a) This section applies to program income not treated elsewhere in this part which arises from or is attributable to an activity while supported by a grant or subgrant but which does not accrue until after the period of grant or subgrant support. An example is proceeds from the sale or rental of a residual inventory of merchandise fabricated or purchased by a grant-supported workshop during the period of support.

(b) The terms of the grant govern the disposition of income subject to this section. If the terms do not treat this kind of income, there are no HHS requirements governing the disposition. A grantee is not prohibited from imposing requirements of its own on the disposition of this kind of income which is earned by its subgrantees provided those requirements are in addition to and not inconsistent with any requirements imposed by the terms of the grant.

§ 74.47 Interest earned on advances of grant funds.

(a) Except when exempted by Federal statute (see paragraph (b) of this section for the principal exemption), grantees shall remit to the Federal Government any interest or other investment income earned on advances of HHS grant funds. This includes any interest or investment income earned by subgrantees and cost-type contractors on advances to them that are attributable to advances of HHS grant funds to the grantee. Unless the grantee receives other instructions from the responsible HHS official, the grantee shall remit the amount due by check or money order payable to the Department of Health and Human Services.

(b) In accordance with the Intergovernmental Cooperation Act of 1968 (Pub. L. 90-577), States, as defined in the act, shall not be accountable to the Federal Government for interest or investment income earned by the State itself, or by its subgrantees, where this income is attributable to grants-in-aid, as defined in the act (42 U.S.C. 4213).[1]

(c) Recipients are cautioned that they are subject to the provisions in § 74.61(e) for minimizing the time between the transfer of advances and their disbursement. Those provisions apply even if there is no accountability to the Federal Government for interest or other investment income earned on the advances.

Subpart G—Cost Sharing or Matching

§ 74.50 Scope of subpart.

(a) This subpart contains rules for satisfying Federal requirements for cost sharing or matching. These rules apply whether the cost sharing or matching is required by Federal statute or by other terms of the grant.

(b) HHS and a grantee may enter into an institutional cost-sharing agreement covering all of HHS's research project grants to that grantee in the aggregate. Except as provided by the institutional cost-sharing agreement, this subpart applies to the satisfaction of the grantee's obligation under the agreement, as well as to the satisfaction of cost-sharing or matching requirements that apply only to a single grant.

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[1] "State" is defined in the Act to include any agency or instrumentality of a State, and the definition does not exclude a hospital or institution of higher education which is such an agency or instrumentality. "Grant-in-aid" is defined in the Act to exclude "payments under research and development contracts or grants which are awarded directly and on similar terms to all qualifying organizations, whether public or private." (42 U.S.C. 4201)

§ 74.51 Definitions.

For purposes of this subpart:

"*Cost sharing or matching*" means the value of third-party in-kind contributions and that portion of the costs of a grant-supported project or program not borne by the Federal Government.

"*Equipment*" has the same meaning given to that term in § 74.132, except that instead of "acquisition cost," the words "market value at the time of donation" shall be substituted.

"*Supplies*" means all tangible personal property other than "equipment" as defined in this section.

"*Third-party in-kind contributions*" means property or services which benefit a grant-supported project or program and which are contributed by non-Federal third parties without charge to the grantee, the subgrantee, or a cost-type contractor under the grant or subgrant.

§ 74.52 Basic rule: Costs and contributions acceptable.

With the qualifications and exceptions listed in § 74.53, a cost-sharing or matching requirement may be satisfied by either or both of the following:

(a) Allowable costs incurred by the grantee, the subgrantee, or a cost-type contractor under the grant or subgrant. This includes allowable costs borne by non-Federal grants or by other cash donations from non-Federal third parties.

(b) The value of third-party in-kind contributions applicable to the period to which the cost-sharing or matching requirement applies.

§ 74.53 Qualifications and exceptions.

(a) *Costs borne by other Federal grants.* (1) Except as provided by Federal statute, a cost-sharing or matching requirement may not be met by costs borne by another Federal grant. This prohibition does not apply to costs borne by general program income earned from a contract awarded under another Federal grant.

(2) For the purposes of this part, general revenue sharing funds under 31 U.S.C. 1221 are not considered a Federal grant. Therefore, in the absence of any provision of Federal statute to the contrary, allowable costs borne by these funds may count towards satisfying a cost-sharing or matching requirement.

(b) *Costs or contributions counted towards other Federal cost-sharing requirements.* Neither costs nor the values of third-party in-kind contributions may count towards satisfying a cost-sharing or matching requirement of an HHS grant if they have been or will be counted towards satisfying a cost-sharing or matching requirement of another Federal grant, a Federal procurement contract, or any other award of Federal funds.

(c) *Costs financed by general program income.* Costs financed by general program income, as defined in § 74.42, shall not count towards satisfying a cost-sharing or matching requirement of the HHS grant supporting the activity giving rise to the income unless the terms of the grant expressly permit the income to be used for cost sharing or matching. (This is the alternative for use of general program income described in § 74.42(d).)

(d) *Records.* Costs and third-party in-kind contributions counting towards satisfying a cost-sharing or matching requirement must be verifiable from the records of recipients or cost-type contractors. These records must show how the value placed on third-party in-kind contributions was arrived at. To the extent feasible, volunteer services shall be supported by the same methods that the organization uses to support the allocability of its regular personnel costs.

(e) *Special standards for third-party in-kind contributions.* (1) Third-party in-kind contributions shall count towards satisfying a cost-sharing or matching requirement only where, if the party receiving the contributions were to pay for them, the payments would be allowable costs.

(2) A third-party in kind contribution shall not count as direct cost sharing or matching where, if the party receiving the contribution were to pay for it, the payment would be an indirect cost. Cost-sharing or matching credit for such contributions shall be given only if the recipient or contractor has established, along with its regular indirect cost rate, a special rate

for allocating to individual projects or programs the value of the contributions. (Information on how to establish these rates can be obtained from the Division of Cost Allocation in any HHS regional office's Regional Administrative Support Center.)

(3) The values placed on third-party in-kind contributions for cost-sharing or matching purposes shall conform to the rules in the succeeding sections of this subpart. If a third-party in-kind contribution is of a type not treated in those sections, the value placed upon it shall be fair and reasonable.

§ 74.54 Valuation of donated services.

(a) *Volunteer services.* Unpaid services provided to a recipient by individuals shall be valued at rates consistent with those ordinarily paid for similar work in the recipient's organization. If the recipient does not have employees performing similar work, the rates shall be consistent with those ordinarily paid by other employers for similar work in the same labor market. In either case, a reasonable amount for fringe benefits may be included in the valuation.

(b) *Employees of other organizations.* When an employer other than a recipient or cost-type contractor furnishes free of charge the services of an employee in the employee's normal line of work, the services shall be valued at the employee's regular rate of pay exclusive of the employer's fringe benefits and overhead costs. If the services are in a different line of work, paragraph (a) of this section shall apply.

§ 74.55 Valuation of donated supplies and loaned equipment or space.

(a) If a third party donates supplies, the contribution shall be valued at the market value of the supplies at the time of donation.

(b) If a third party donates the use of equipment or space in a building but retains title, the contribution shall be valued at the fair rental rate of the equipment or space.

§ 74.56 Valuation of donated equipment, buildings, and land.

If a third party donates equipment, buildings, or land, and title passes to a recipient, the treatment of the donated property shall depend upon the purpose of the grant or subgrant, as follows:

(a) *Awards for capital expenditures.* If the purpose of the grant or subgrant is to assist the recipient in the acquisition of property, the market value of that property at the time of donation may be counted as cost sharing or matching.

(b) *Other awards.* If assisting in the acquisition of property is not the purpose of the grant or subgrant, the following rules apply:

(1) If approval is obtained from the awarding party, the market value at the time of donation of the donated equipment or buildings and the fair rental rate of the donated land may be counted as cost sharing or matching. In the case of a subgrant, the terms of the HHS grant may require that the approval be obtained from the granting agency as well as the grantee. In all cases, the approval may be given only if a purchase of the equipment or buildings or a purchase or rental of the land would be approved as an allowable direct cost.

(2) If approval is not obtained under paragraph (b)(1) of this section, no amount may be counted for donated land, and only depreciation or use allowances may be counted for donated equipment and buildings. The depreciation or use allowances for this property are not treated as third-party in-kind contributions. Instead, they are treated as costs incurred by the recipient. They are computed and allocated (usually as indirect costs) in accordance with the cost principles specified in Subpart Q of this part, in the same way as depreciation or use allowances for purchased equipment and buildings. The amount of depreciation or use allowances for donated equipment and buildings is based on the property's market value at the time it was donated.

§ 74.57 Appraisal of real property.

In some cases under §§ 74.55 and 74.56, it will be necessary to establish the market value of land or a building or the fair rental rate of land or of space in a building. In these cases, the granting agency may require that the market value or fair rental rate be established by a certified real property appraiser (or by a representative of the U.S. General Services Administration, if available) and that the value or rate be certified by a responsible official of the party to which the property or its use is donated. For subgrants, this requirement may also be imposed by the grantee.

Subpart H—Standards for Grantee and Subgrantee Financial Management Systems and Audits

§ 74.60 Scope of subpart.

(a) This subpart contains standards for financial management systems and non-Federal audits of recipients.

(b) Awarding parties may not impose on recipients additional financial management standards or requirements concerning non-Federal audits. They may, however, provide recipients with suggestions and assistance on these subjects

[45 FR 35329, May 27, 1980]

§ 74.61 Financial Management Standards.

Grantees and subgrantees shall meet the following standards for their grant and subgrant financial management systems.

(a) *Financial reporting.* Accurate, current, and complete disclosure of the financial results of each project or program shall be made in accordance with the financial reporting requirements of the grant or subgrant. The terms of grants and subgrants shall not require financial reporting on the accrual basis if the recipient's accounting system is maintained on the cash basis. When accrual reporting is statutorily required, a recipient whose accounting system is not maintained on that basis shall not be required to convert it to the accrual basis; the recipient may develop the accrual information through an analysis of the documentation on hand.

(b) *Accounting records.* Records which identify adequately the source and application of funds for grant- or subgrant-supported activities shall be maintained. These records shall contain information pertaining to grant or subgrant awards, authorizations, obligations, unobligated balances, assets, outlays, income, and, if the recipient is a government, liabilities.

(c) *Internal control.* Effective control and accountability shall be maintained for all grant or subgrant cash, real and personal property covered by Subpart O of this part, and other assets. Recipients shall adequately safeguard all such property and shall assure that it is used solely for authorized purposes.

(d) *Budgetary control.* The actual and budgeted amounts for each grant or subgrant shall be compared. If appropriate or specifically required, recipients shall relate financial information to performance or productivity data, including the production of unit cost information. If unit cost data are required, estimates based on available documentation will be accepted whenever possible.

(e) *Advance payments.* Procedures shall be established to minimize the time elapsing between the advance of Federal grant or subgrant funds and their disbursement by the recipient. When advances are made by a letter-of-credit method, the recipient shall make drawdowns as close as possible to the time of making disbursements. Grantees advancing cash to subgrantees shall conform sustantially to the same standards of timing and amount as apply to advances by Federal agencies to grantees, including requirements for timely reporting of cash disbursements and balances. (See Subpart K of this part.)

(f) *Allowable costs.* Procedures shall be established for determining the reasonableness, allowability, and allocability of costs in accordance with the applicable cost principles prescribed by Subpart Q of this part and the terms of the grant.

(g) *Source documentation.* Accounting records shall be supported by source documentation such as cancelled checks, paid bills, payrolls, contract and subgrant award documents, etc.

(h) *Audit resolution.* Each recipient shall follow a systematic method to assure timely and appropriate resolution of audit findings and recommendations.

[45 FR 22576, Apr. 3, 1980, as amended at 45 FR 35329, May 27, 1980]

§ 74.62 Non-Federal audits.

(a) *Governmental recipients*—(1) *Fiscal periods of recipients beginning before January 1, 1985.* Recipients that are governments shall comply with the requirements concerning non-Federal audits in Attachment P to OMB Circular A-102 (October 1979).[1]

(2) *Fiscal periods of recipients beginning on or after January 1, 1985.* Recipients that are governments shall comply with OMB Circular A-128, including any amendments published in the FEDERAL REGISTER by OMB. The Circular is codified verbatim as Appendix J to this part.

(3) *Submission of audit reports.* All copies of audit reports that a recipient is required under OMB Circular A-128 to submit to HHS shall be addressed to the HHS Regional Inspector General for Audit responsible for the HHS region in which the recipient is located. The HHS Office of Inspector General will distribute copies as appropriate within the Department. Recipients therefore are not required to send their audit reports to any HHS officials, other than the responsible Regional Inspector General for Audit.

(b) *All other recipients.* Recipients that are not governments shall comply with the requirements concerning non-Federal audits in OMB Circular No. A-110, including any amendments to those requirements published in the FEDERAL REGISTER by OMB.[1]

[45 FR 35329, May 27, 1980; 45 FR 36415, May 30, 1980, as amended at 50 FR 31716, Aug. 6, 1985; 53 FR 8079, Mar. 11, 1988]

Subpart I—Financial Reporting Requirements

§ 74.70 Scope and applicability of subpart.

(a) This subpart prescribes requirements and forms for grantees to report financial information to HHS, and to request grant payments when a letter of credit is not used.

(b) This subpart need not be applied by grantees in dealing with their subgrantees. However, grantees are encouraged not to impose on subgrantees more burdensome requirements than HHS imposes on grantees.

§ 74.71 Definitions.

As used in this subpart or in the forms identified by this subpart:

"*Accrued expenditures*" are the charges by grantee during a given period requiring the provision of funds for: (a) Goods and other tangible property received; (b) services performed by employees, contractors, subgrantees, and other payees; and (c) amounts "becoming owed" for which no current services or performance is required, such as annuities, insurance claims, and other benefit payments.

"*Accrued income*" is the sum of (a) earnings during a given period from services performed by the grantee and from goods and other tangible property delivered to purchasers, and (b) amounts becoming owed to the grantee for which no current services or performance is required by the grantee.

"*Federal funds authorized*" means the total amount of Federal funds obligated by the Federal Government and authorized for use by the grantee.

"*In-kind contributions*" means "third-party in-kind contributions" as defined in Subpart G of this part.

"*Obligations*" are the amounts of orders placed, contracts and subgrants awarded, services received, and similar transactions during a given period, which will require payment during the same or a future period.

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[1] OMB Circulars A-102 and A-110 are available on request from the Office of Management and Budget, Publications Room, New Executive Office Building, Washington, D.C. 20503. Here is a summary of some of the main provisions concerning non-Federal audits in those two circulars:

(1) Each recipient must have itself audited by non-Federal auditors at least every two years.

(2) The recipient's auditors must meet certain standards of independence.

(3) The audit is to be performed on an organization-wide basis, with approprpiate sampling of grant-related transactions. Awarding parties may not impose grant-by-grant (or subgrant-by-subgrant) audit requirements.

"Outlays" are charges made to the grant project or program. Outlays may be reported on a cash or accrual basis.

"Program income" has the same meaning it has in Subpart F of this part.

"Unobligated balance" is the portion of the Federal funds authorized which has not been obligated by the grantee and is determined by deducting the grantee's cumulative obligations from the cumulative Federal funds authorized.

"Unliquidated obligations", for reports prepared on a cash basis, are the amount of obligations incurred by the grantee that has not been paid. For reports prepared on an accrued expenditure basis, they are the amount of obligations incurred by the grantee for which an outlay has not been recorded.

§ 74.72 General.

(a) Except as provided in paragraphs (d) and (e) of this section, grantees shall use only the forms specified in §§ 74.73 through 74.76, and such supplementary or other forms as may from time to time be authorized by OPAL, for:

(1) Submitting grant financial reports to granting agencies, or

(2) Requesting advances or reimbursements when letters of credit are not used.

(b) Grantees shall follow all applicable standard instructions issued by OMB for use in connection with the forms specified in §§ 74.73 through 74.76. Granting agencies may issue substantive supplementary instructions only with the approval of OPAL. Granting agencies may shade out or instruct the grantee to disregard any line item that the granting agency finds unnecessary for its decision making purposes.

(c) Grantees will not be required to submit more than the original and two copies of forms required under this subpart.

(d) Granting agencies may provide computer outputs to grantees to expedite or contribute to the accuracy of reporting. Granting agencies may accept the required information from grantees in machine usable format or computer printouts instead of prescribed formats.

(e) When a granting agency has determined that a grantee's accounting system does not meet the standards for financial management systems contained in Subpart H of this part, it may require financial reports with more frequency or more detail (or both), upon written notice to the grantee (without regard to § 74.7), until such time as the standards are met.

(f) HHS may waive any report required by this subpart if not needed.

(g) Granting agencies may extend the due date for any financial report upon receiving a justified request from the grantee.

[45 FR 22576, Apr. 3, 1980, as amended at 47 FR 53013, Nov. 24, 1982]

§ 74.73 Financial Status Report.

(a) *Form.* Grantees shall use Standard Form 269, Financial Status Report, to report the Status of funds for all nonconstruction grants.

(b) *Accounting basis.* Each grantee shall report program outlays and program income on the same accounting basis, i.e., cash or accrued expenditure (accrual), which it uses in its accounting system.

(c) *Frequency.* The granting agency may prescribe the frequency of the report for each project or program. However, the report shall not be required more frequently than quarterly except as provided in §§ 74.7 and 74.72(e). If the granting agency does not specify the frequency of the report, it shall be submitted annually. A final report shall be required upon expiration or termination of grant support.

(d) *Due date.* When reports are required on a quarterly or semiannual basis, they shall be due 30 days after the reporting period. When required on an annual basis, they shall be due 90 days after the grant year. Final reports shall be due 90 days after the expiration or termination of grant support.

§ 74.74 Federal Cash Transactions Report.

(a) *Form.* (1) For grants paid by letters of credit (or Treasury check advances) through any HHS payment office except the Departmental Federal Assistance Financing System (DFAFS), the grantee shall submit to the payment office Standard Form 272, Federal Cash Transactions Report, and when necessary, its continuation sheet, Standard Form 272a. For grants paid by DFAFS, the grantee shall submit DFAFS Report 27, Recipient Report of Expenditures, to DFAFS.

(2) These reports will be used by the HHS payment office to monitor cash advanced to grantees and to obtain disbursement or outlay information for each grant from grantees. The format of the report may be adapted as appropriate when reporting is to be accomplished with the assistance of automatic data processing equipment: *Provided*, That the information to be submitted is not changed in substance.

(b) *Forecasts of Federal cash requirements.* Forecasts of Federal cash requirements may be required in the "Remarks" section of the report.

(c) *Cash in hands of secondary recipients.* When considered necessary and feasible by the responsible HHS payment office, grantees may be required to report the amount of cash subadvances in excess of three days' needs in the hands of their subgrantees or contractors and to provide short narrative explanations of actions taken by the grantee to reduce the excess balances.

(d) *Frequency and due date.* Grantees shall submit the report no later than 15 working days following the end of each quarter. However, where a letter of credit authorizes advances at an annualized rate of one million dollars or more, the HHS payment office may require the report to be submitted within 15 working days following the end of each month.

§ 74.75 Request for Advance or Reimbursement.

(a)(1) *Advance payments.* Requests for Treasury check advance payments shall be submitted on Standard Form 270, Request for Advance or Reimbursement. (This form is not used for drawdowns under a letter of credit or when Treasury check advance payments are made to the grantee automatically on a predetermined basis.)

(2) *Reimbursements.* Requests for reimbursement under non-construction grants shall also be submitted on Standard Form 270. (For reimbursement requests under construction grants, see § 74.76(a).)

(b) The frequency for submitting payment requests is treated in § 74.96.

§ 74.76 Outlay report and request for reimbursement for construction programs.

(a) *Construction grants paid by reimbursement method.* (1) Requests for reimbursement under construction grants shall be submitted on Standard Form 271, Outlay Report and Request for Reimbursement for Construction Programs. Granting agencies may, however, prescribe the Request for Advance or Reimbursement form specified in § 74.75 instead of this form.

(2) The frequency for submitting reimbursement requests is treated in § 74.96.

(b) *Construction grants paid by letter of credit or Treasury check advance.* (1) When a construction grant is paid by letter of credit or Treasury check advances, the grantee shall report its outlays to the granting agency using Standard Form 271, Outlay Report and Request for Reimbursement for Construction Programs. The granting agency will provide any necessary special instruction. However, frequency and due date shall be governed by § 74.73(c) and (d).

(2) When a construction grant is paid by Treasury check advances based on periodic requests from the grantee, the advances shall be requested on the form specified in § 74.75.

(3) The granting agency may substitute the Financial Status Report specified in § 74.73 for the Outlay Report and Request for Reimbursement.

(c) *Accounting basis.* The accounting basis for the Outlay Report and Request for Reimbursement for Construction Programs shall be governed by § 74.73(b).

Subpart J—Monitoring and Reporting of Program Performance

§ 74.80 Scope of subpart.

This subpart sets forth the procedures for monitoring and reporting program performance of recipients. These procedures are designed to place reliance on recipients to manage the day-to-day operations of their grant- and subgrant-supported activities.

§ 74.81 Monitoring by recipients.

Recipients shall monitor the performance of grant- and subgrant-supported activities. They shall review each program, function, or activity to assure that adequate progress is being made towards achieving the goals of the grant or subgrant.

§ 74.82 Performance reports under nonconstruction grants.

(a) Where the granting agency determines that performance information sufficient to meet its programmatic needs will be available from subsequent applications, the granting agency will require the grantee to submit a performance report only upon expiration or termination of grant support. This report will be due on the same date as the final financial Status Report unless waived by the granting agency. Note that the "Application for Federal Assistance (Nonconstruction Programs)" prescribed by subpart N of this part, when used to request continued support, provides information substantially equivalent to a performance report.

(b) Except as provided in paragraph (a) of this section, grantees shall submit annual performance reports unless the granting agency requires quarterly or semiannual reports. Annual reports shall be due 90 days after the grant year; quarterly or semiannual reports shall be due 30 days after the reporting period. A final performance report shall be due 90 days after the expiration or termination of grant support. Granting agencies may extend the due date for any performance report upon receiving a justified request from the grantee. In addition, granting agencies may waive the requirement for any performance report which is not needed.

(c) The content of performance reports shall conform to any instructions issued by the granting agency, including, to the extent appropriate to the particular grant, a brief presentation of the following for each program, function, or activity involved:

(1) A comparison of actual accomplishments to the goals established for the period. Where the output of the project or program can be readily expressed in numbers, a computation of the cost per unit of output may be required if that information will be useful.

(2) The reasons for slippage if established goals were not met.

(3) Other pertinent information including, when appropriate, analysis and explanation of unexpectedly high overall or unit costs.

(d) Grantees will not be required to submit more than the original and two copies of performance reports.

(e) Grantees shall adhere to the standards in paragraphs (a) through (d) of this section in prescribing performance reporting requirements for subgrantees.

§ 74.83 Performance reports under construction grants.

In general, awarding parties rely heavily on on-site technical inspection and certified percentage-of-completion data to keep themselves informed as to progress under construction grants and subgrants. Formal performance reports to supplement those sources of information shall be required only if considered necessary by the awarding party, and in no case more frequently than quarterly.

§ 74.84 Significant developments between scheduled reporting dates.

Between the scheduled performance reporting dates, events may occur which have significant impact upon the grant- or subgrant-supported activity. In such cases, the recipient shall inform the awarding party as soon as the following types of conditions become known:

(a) Problems, delays, or adverse conditions which will materially impair the ability to attain the objective of the award. This disclosure shall be accompanied by a statement of the action taken, or contemplated, and any assistance needed to resolve the situation.

(b) Favorable developments which enable meeting time schedules and goals sooner or at less cost than anticipated or producing more beneficial results than originally projected.

§ 74.85 Site visits.

Site visits may be made as necessary by representatives of HHS to:

(a) Review program accomplishments and management control systems.

(b) Provide such technical assistance as may be required.

Subpart K—Grant and Subgrant Payment Requirements

§ 74.90 Scope of subpart.

This subpart prescribes the basic standard and the methods under which HHS will make grant payments to grantees, and grantees will make subgrant payments to their subgrantees.

§ 74.91 Definitions.

As used in this subpart:

"*Advance by Treasury check*" is a payment made by a Treasury check to a grantee, upon its periodic request or through the use of predetermined payment schedules, before payments are made by the grantee.

"*Letter of credit*" is an instrument certified by an authorized official which authorizes a recipient to draw funds needed for immediate disbursement in accordance with Treasury Circular No. 1075.

"*Percentage of completion method*" refers to a system under which payments are made for construction work according to the percentage of completion of the work, rather than to the grantee's rate of disbursements.

§ 74.92 Basic standard.

(a) Methods and procedures for making payments to recipients shall minimize the time elapsing between the transfer of funds and the recipient's disbursements.

(b) Except as provided in § 74.47(b), public and private nonprofit institutions of higher education, public and private nonprofit hospitals, and other private nonprofit grantees shall maintain advances of Federal funds in interest bearing accounts. Interest earned on Federal advances deposited in such accounts shall be remitted promptly, but at least quarterly, to the Federal agencies that provided the funds. Interest amounts up to $100 per recipient fiscal year may be retained by the recipient for administrative expense. (The $100 pertains to the total interest earned on all Federal advances.)

[45 FR 22576, Apr. 3, 1980, as amended at 52 FR 33240, Sept. 2, 1987]

§ 74.93 Payment methods under nonconstruction grants.

(a) Letters of credit will be used to pay HHS grantees when all of the following conditions exist:

(1) There is or will be a continuing relationship between the grantee and the HHS payment office for at least a year and the total amount of advances to be received from the HHS payment office is $120,000 or more per year,

(2) The grantee has maintained, or demonstrated to HHS the willingness and ability to maintain, procedures that minimize the time elapsing between the transfer of funds from the Treasury and their disbursement by the grantee, and

(3) The grantee's financial management system meets the standards for fund control and accountability in Subpart H of this part.

(b) Advances by Treasury check will be used, in accordance with Treasury Circular No. 1075, when the grantee does not meet the requirements in paragraph (a)(1) of this section but does meet the requirements in paragraphs (a) (2) and (3) of this section.

(c) Reimbursement by Treasury check will be preferred method when the requirements of either paragraph (a)(2) or paragraph (a)(3) of this section are not met. This method may also be used when the major portion of the program is accomplished through private market financing or Federal loans, and the Federal grant assistance constitutes a minor portion of the program.

§ 74.94 Payment methods under construction grants.

(a) Reimbursement by Treasury check shall be the preferred method when the grantee does not meet the requirements specified in § 74.93(a) (2) or (3), and may be used for any HHS construction grant unless HHS has entered into an agreement with the grantee to use a letter of credit for all HHS grants, including construction grants.

(b) When the reimbursement by Treasury check method is not used, § 74.93 (a) and (b) shall apply to the construction grant. Implementing procedures under § 74.93 (a) and (b) will be insofar as possible the same for construction grants as for nonconstruction grants awarded to the same grantee.

(c) HHS will not use the percentage of completion method to pay its construction grants. The grantee may use that method to pay its construction contractor, but if it does, HHS's payments to the grantee will nevertheless be based on the grantee's actual rate of disbursements.

§ 74.95 Withholding of payments.

(a) Unless otherwise required by Federal statute, payments for proper charges incurred by grantees will not be withheld unless (1) the grantee has failed to comply with Federal reporting requirements or (2) the grant is suspended pursuant to § 74.114 or (3) the grantee owes money to the United States and collection of the debt by withholding grant payments will not impair the accomplishment of the objectives of any grant program sponsored by the United States.

(b) Cash withheld for failure to comply with reporting requirements but without suspension of the grant will be released to the grantee upon subsequent compliance. When a grant is suspended, payment adjustments will be made in accordance with § 74.114. When a debt is to be collected, HHS may withhold payments or require appropriate accounting adjustments to recorded grant cash balances for which the grantee is accountable to the Federal Government, in order to liquidate the indebtedness.

§ 74.96 Requesting advances or reimbursements.

(a) If advances are made by Treasury check and the advances are not prescheduled, the grantee shall submit its requests for payment monthly. Less frequent requests are not permitted because they would result in advances covering excessive periods of time. The grantee shall not request advances in excess of the Federal share of reasonable estimates of its outlays for the month covered. The grantee shall make these estimates on a cash basis, even if it uses an accrual accounting system.

(b) If payments are made through reimbursement by Treasury check:

(1) The grantee may submit its requests for reimbursement monthly and may submit them more often if authorized. The grantee will be paid as promptly as possible, ordinarily within 30 days after receipt of a proper request for reimbursement.

(2) The grantee shall not request reimbursement for the Federal share of amounts withheld from contractors to ensure satisfactory completion of work until after it makes those payments. To meet this requirement, a grantee with an accural accounting system need not convert to cash basis accounting. It may bill in general on an accrued cost basis, handling these retained amounts as adjustments in the billing system.

(c) The forms for requesting advances or reimbursements are identified in Subpart I of this part.

[45 FR 37667, June 3, 1980]

§ 74.97 Payments to subgrantees.

Grantees shall observe the requirements of this subpart in making (or withholding) payments to subgrantees, with the following exceptions:

(a) Advance payment by check may be used instead of letter of credit;

(b) The forms specified in Subpart I of this part for requesting advances and reimbursements are not required to be used by subgrantees; and

(c) The reimbursement by check method may be used to pay any construction subgrant, whether or not HHS has agreed to use a letter of credit for all direct HHS grants to that same recipient.

Subpart L—Programmatic Changes and Budget Revisions

§ 74.100 Scope and applicability of this subpart.

(a) *Scope.* This subpart deals with prior approval requirements for post-award programmatic changes and budget revisions by recipients.

(b) *Exemption of mandatory grants.* Sections 74.103 through 74.106 do not apply to programmatic changes or budget revisions made by grantees under State plan or other grants which the granting agency is required by law to award if the applicant meets all applicable requirements for entitlement. (These are generally called "mandatory" or "formula" grants.)

(c) *Exemption of certain subgrants.* Sections 74.103 through 74.106 do not apply to subgrants from States to their local governments under a mandatory or formula grant, if the local government is not required to apply for the subgrant on a project basis. Generally, such exempt subgrants will occur under a State plan which provides for local administration of a State-wide program under State supervision.

§ 74.101 Relationship to cost principles.

The cost principles prescribed by Subpart Q of this part contain requirements for prior approval of certain types of costs (see § 74.177). Except when waived, those requirements apply to all grants and subgrants even if §§ 74.103 through 74.106 do not.

[47 FR 53013, Nov. 24, 1982]

§ 74.102 Prior approval procedures.

(a) *For grants.* When requesting a prior approval required by this subpart, grantees shall address their requests to the responsible grants officer of the granting agency. Approvals shall not be valid unless they are in writing and signed by either the grants officer, the head of the granting agency, or the head of the granting agency's regional office.

(b) *For subgrants.* Grantees shall be responsible for reviewing requests from their subgrantees for the approvals required by this subpart and for giving or denying the approval. A grantee shall not approve any action which is inconsistent with the purpose or terms of the Federal grant. If an action by a subgrantee will result in a change in the overall grant project or budget requiring granting agency approval, the grantee shall obtain that approval before giving its approval to the subgrantee. Approvals shall not be valid unless they are in writing and signed by an authorized official of the grantee.

(c) *Timing.* Within 30 days from the date of receipt of a request for approval, the approval authority shall review the request and notify the recipient of its decision. If the request for approval is still under consideration at the end of 30 days, the approval authority shall inform the recipient in writing as to when to expect the decision.

§ 74.103 Programmatic changes.

(a) *Scope.* This section contains requirements for prior approval of departures, other than budget revisions, from approved project plans. In addition to the requirements in this section, awarding parties may require prior approval for other kinds of programmatic changes to an approved grant or subgrant project.

(b) *Changes to project scope or objectives.* The recipient shall obtain prior approval for any change to the scope or objectives of the approved project. (For construction projects, any material change in approved space utilization or functional layout shall be considered a change in scope.)

(c) *Changes in key people.* The recipient of a grant or subgrant for research (or any other kind of grant or subgrant if the terms of the award make this rule applicable) shall obtain prior approval:

(1) To continue the project during any continuous period of more than 3 months without the active direction of an approved project director or principal investigator; or

(2) To replace the project director or principal investigator (or any other persons named and expressly identified as key project people in the notice of grant or subgrant award) or to permit any such people to devote substantially less effort to the project than was anticipated when the grant or subgrant was awarded.

(d) *Other programmatic changes.* The following shall require prior approval except to the extent explicitly included in the project plan as approved by the awarding party at the time of award:

(1) Providing financial assistance to a third party by subgranting or any other means.

(2) Tranferring to a third party, by contracting or any other means, the actual performance of the substantive programmatic work. The term "substantive programmatic work" means activities which are central to carrying out the purpose of the project, and not merely incidental. Transfer of substantive programmatic work does not include purchase of supplies, materials, or equipment; acquisition of general or incidental support services; obtaining advice; or transfer of activities whose cost is treated as an indirect cost.

(3) Providing medical care to individuals under research grants.

§ 74.104 Budgets generally.

(a) *Definitions.* In this subpart:

(1) "Budget" means the recipient's financial plan for carrying out the project or program.

(2) "Approved budget" means a budget (including any revised budget) which has been approved by the awarding party.

(b) *Research project budgets.* For research projects, approved budgets shall not include the recipient's share of project costs.

(c) *Non-research project budgets.* For non-research projects which involve cost sharing or matching, approved budgets shall ordinarily consist of a single set of figures covering total project cost (the sum of the awarding party's share and the recipient's share). However, the awarding party may specify that the recipient's share not be included in the approved budget. In no case, however, shall the approved budget be in the form of a separate set of figures for each share.

(d) *Subdivision by programmatic segments.* Some grants and subgrants encompass two or more programmatic segments (such as discrete programs, projects, functions, or types of activities). In these cases, the awarding party may require that the approved budget be subdivided to show the anticipated cost of each programmatic segment.

§ 74.105 Budget revisions—nonconstruction projects.

(a) Except as provided in paragraph (b) of this section, the recipient of a grant or subgrant having an approved budget shall obtain prior approval for any budget revision which will:

(1) Involve transfer of amounts budgeted for indirect costs to absorb increases in direct costs, or

(2) Involve transfer of amounts previously budgeted for student support (tuition waivers, stipends, and other payments to or for trainees), or

(3) Result in a need for the award of additional funds, e.g., an increase in the base upon which indirect costs are calculated which will increase allocable indirect costs and result in a claim for a supplementary award.

(b) Any or all of the prior approval requirements in paragraph (a) of this section may be waived by the awarding party.

(c) Except as provided in §§ 74.107 and 74.177, other budget changes under nonconstruction grants do not require approval.

[45 FR 22576, Apr. 3, 1980, as amended at 47 FR 53013, Nov. 24, 1982]

§ 74.106 Budget revisions—construction projects.

Unless provided otherwise by the terms of the grant or subgrant, revisions to construction project budgets do not require approval.

§ 74.107 Construction and nonconstruction work under the same grant or subgrant.

When a grant or subgrant provides support for both construction and nonconstruction work, the awarding party may require prior approval before any fund or budget transfers between the two types of work.

§ 74.108 Authorized funds exceeding needs.

The recipient shall notify the awarding party promptly whenever the amount of grant or subgrant authorized funds is expected to exceed needs by more than $5,000 or 5 percent of the grant or subgrant, whichever is greater. This notification will not be required under continuing grants or subgrants if the application for the next period's funding will include an estimate of what the unobligated balance of authorized funds will be at the end of the current period.

Subpart M—Grant and Subgrant Closeout, Suspension, and Termination

§ 74.110 Definitions.

"Grant closeout" means the process by which a granting agency determines that all applicable administrative actions and all required work of the grant have been completed by the grantee and the granting agency.

"Suspension" of a grant means temporary withdrawal of the grantee's authority to obligate grant funds pending corrective action by the grantee or a decision to terminate the grant.

"Termination" of a grant means permanent withdrawal of the grantee's authority to obligate previously awarded grant funds before that authority would otherwise expire. It also means the voluntary relinquishment of that authority by the grantee. "Termination" does not include:

(a) Withdrawal of funds awarded on the basis of the grantee's underestimate of the unobligated balance in a prior period;

(b) Refusal by the granting agency to extend a grant or award additional funds (such as refusal to make a competing or noncompeting continuation, renewal, extension, or supplemental award);

(c) Withdrawal of the unobligated balance as of the expiration of a grant;

(d) Annulment, i.e., voiding, of a grant upon determination that the award was obtained fraudulently, or was otherwise illegal or invalid from inception.

§ 74.111 Closeout.

(a) Each grant shall be closed out as promptly as is feasible after expiration or termination.

(b) In closing out HHS grants, the following shall be observed:

(1) Upon request, HHS shall promptly pay the grantee for any allowable reimbursable costs not covered by previous payments.

(2) The grantee shall immediately refund or otherwise dispose of, in accordance with instructions from HHS, any unobligated balance of cash advanced to the grantee.

(3) The grantee shall submit, within 90 days of the date of expiration or termination, all financial, performance, and other reports required by the terms of the grant. HHS may extend the due date for any report upon receiving a justified request from the grantee, and may waive any report which is not needed.

(4) The granting agency shall make a settlement for any upward or downward adjustment of the Federal share of costs, to the extent called for by the terms of the grant.

(c)(1) The closeout of a grant does not affect the retention period for, or Federal rights of access to, grant records. See Subpart D of this part.

(2) If a grant is closed out without audit, the granting agency retains the right to disallow and recover an appropriate amount after fully considering any recommended disallowances resulting from an audit which may be conducted later.

(3) The closeout of a grant does not affect the grantee's responsibilities with respect to property under Subpart O of this part, or with respect to any program income for which the grantee is still accountable under Subpart F of this part.

§ 74.112 Amounts payable to the Federal Government.

For each grant, the following sums shall constitute a debt or debts owed by the grantee to the Federal Government, and shall, if not paid upon demand, be recovered from the grantee or its successor or assignees by setoff or other action as provided by law:

(a) Any grant funds paid to the grantee by the Federal Government in excess of the amount to which the grantee is finally determined to be entitled under the terms of the grant;

(b) Any interest or other investment income earned on advances of grant funds which is due the Federal Government pursuant to § 74.47;

(c) Any royalties or other special classes of program income which, under the terms of the grant, are required to be remitted to the Federal Government (see Subpart F of this part);

(d) Any amounts due the Federal Government under Subpart O of this part; and

(e) Any other amounts finally determined to be due the Federal Government under the terms of the grant.

§ 74.113 Violation of terms.

(a) When a grantee has materially failed to comply with the terms of a grant, the granting agency may suspend the grant, in accordance with § 74.114, terminate the grant for cause, as provided in § 74.115, or take such other remedies as may be legally available and appropriate in the circumstances.

(b) If a project or program is supported over two or more funding periods, a grant may be suspended or terminated in the current period for failure to submit a report still due from a prior period.

§ 74.114 Suspension.

(a) When a grantee has materially failed to comply with the terms of a grant, the granting agency may, upon reasonable notice to the grantee, suspend the grant in whole or in part. The notice of suspension will state the reasons for the suspension, any corrective action required of the grantee, and the effective date. The suspension may be made effective at once if a delayed effective date would be unreasonable considering the granting agency's responsibilities to protect the Federal Government's interest. Suspensions shall remain in effect until the grantee has taken corrective action satisfactory to the granting agency, or given evidence satisfactory to the granting agency that such corrective action will be taken, or until the granting agency terminates the grant.

(b) New obligations incurred by the grantee during the suspension period will not be allowed unless the granting agency expressly authorizes them in the notice of suspension or an amendment to it. Necessary and otherwise allowable costs which the grantee could not reasonably avoid during the suspension period will be allowed if they result from obligations properly incurred by the grantee before the effective date of the suspension and not in anticipation of suspension or termination. At the discretion of the granting agency, third-party in-kind contributions applicable to the suspension period may be allowed in satisfaction of cost sharing or matching requirements.

(c) Appropriate adjustments to payments under the suspended grant will be made either by withholding subsequent payments or by not allowing the grantee credit for disbursements made in payment of unauthorized obligations incurred during the suspension period.

§ 74.115 Termination.

(a) *Termination for cause.* The granting agency may terminate any grant in whole, or in part, at any time before the date of expiration, whenever it determines that the grantee has materially failed to comply with the terms of the grant. The granting agency shall promptly notify the grantee in writing of the determination and the reasons for the termination, together with the effective date.

(b) *Termination on other grounds.* Except as provided in paragraph (a) of this section, grants may be terminated in whole or in part only as follows:

(1) By the granting agency with the consent of the grantee, in which case the two parties shall agree upon the termination conditions, including the effective date and in the case of partial terminations, the portion to be terminated, or

(2) By the grantee, upon written notification to the granting agency, setting forth the reasons for such termi-

nation, the effective date, and in the case of partial terminations, the portion to be terminated. However, if, in the case of a partial termination, the granting agency determines that the remaining portion of the grant will not accomplish the purposes for which the grant was made, the granting agency may terminate the grant in its entirety under either paragraph (a) or paragraph (b)(1) of this section.

(c) *Termination settlements.* When a grant is terminated, the grantee shall not incur new obligations for the terminated portion after the effective date, and shall cancel as many outstanding obligations as possible. The granting agency shall allow full credit to the grantee for the Federal share of the noncancellable obligations properly incurred by the grantee prior to termination.

§ 74.116 Applicability to subgrants.

Grantees shall adhere to the same standards regarding closeout, suspension, and termination of subgrants as are prescribed in this subpart for granting agencies.

Subpart N—Forms for Applying for Grants

§ 74.120 Scope of subpart.

(a) This subpart prescribes forms and instructions to be used by governmental organizations (except hospitals and institutions of higher education operated by a government) in applying to HHS for grants. This subpart is not applicable, however, to mandatory or formula grant programs which do not require applicants to apply to HHS for funds on a project basis.

(b) This subpart permits granting agencies to prescribe the form of applications by nongovernmental organizations (including hospitals and institutions of higher education operated by a government), but prescribes the use of a standard facesheet for certain of these applications.

(c) This subpart applies only to applications for grants, and is not required to be applied by grantees in dealing with applicants for subgrants. However, grantees are encouraged not to adopt more detailed or burdensome application requirements for subgrants.

§ 74.121 Authorized forms and instructions for governmental organizations.

(a) In applying to HHS for grants, governments shall use only the forms specified in §§ 74.122 through 74.126, and such supplementary or other forms as may from time to time be prescribed by the granting agency with the approval of OPAL.

(b) Governments will not be required to submit more than the original and two copies of their applications.

(c) Governments shall follow all applicable standard instructions promulgated by OMB for use in connection with the forms specified in §§ 74.122 through 74.126. Granting agencies may specify and describe the programs, functions, or activities that will be used to plan, budget, and evaluate the work under a grant. Other supplementary instructions may be issued only with the approval of OPAL. For any form, the granting agency may shade out or instruct the applicant to disregard any line item that is not needed.

(d) When a government applies for additional funding (such as a continuation or supplemental award) or amends a previously submitted application, only the facesheet and any other affected pages need be submitted. Previously submitted pages whose information is still current need not be resubmitted.

[45 FR 22576, Apr. 3, 1980, as amended at 47 FR 53013, Nov. 24, 1982]

§ 74.122 Preapplications for Federal Assistance for governmental organizations.

(a) When a preapplication is submitted by a government, the preapplication for Federal assistance form prescribed by OMB Circular A-102 shall be used. The purposes of preapplications shall be to:

(1) Establish communication between the applicant and the granting agency;

(2) Determine the applicant's eligibility;

(3) Determine how well the project can compete with similar applications from others in order to discourage proposals which have little or no chance for Federal funding before applicants incur significant expenditures for preparing an application.

(b) Preapplication shall be mandatory when the potential applicant is a government and the proposed project (1) is for construction, land acquisition, or land development, and (2) would require more than $100,000 of Federal funding. The granting agency may require preapplications regardless of the type of project and regardless of the estimated amount of Federal funding. In addition, any government may submit a preapplication even when not required by the granting agency.

§ 74.123 Notice of preapplication review action for governmental organizations.

The notice of preapplication review action form prescribed by Attachment M of OMB Circular No. A-102 will be used by granting agencies to inform governmental applicants of the results of the review of the preapplications submitted to them. The granting agency will send a notice to the applicant ordinarily within 45 days of the receipt of the preapplication form. If the review cannot be made within 45 days, the applicant will be informed by letter as to when the review will be completed.

§ 74.124 Application for Federal assistance (nonconstruction programs) for governmental organizations.

The applicant for Federal assistance (nonconstruction programs) form prescribed by Attachment M of OMB Circular No. A-102 shall be used by governments in applying for any grant to which this subpart is applicable except where a form specified in § 74.125 or § 74.126 is to be used.

§ 74.125 Application for Federal assistance (for construction programs) for governmental organizations.

The applicant for Federal assistance (for construction programs) form prescribed by Attachment M of OMB Circular No. A-102 shall be used by governments in applying for any grant whose purpose is soley or primarily construction, land acquisition, or land development.

§ 74.126 Application for Federal assistance (short form) for governmental organizations.

The applicant for Federal assistance (short form) form prescribed by Attachment M of OMB Circular No. A-102 shall be used by governments in applying for any single-purpose one-time grant of less than $10,000 not requiring clearinghouse review, an environmental impact statement, or the relocation of persons, businesses, or farms. Granting agencies may, at their discretion, authorize or prescribe this form for applications for larger amounts.

§ 74.127 Authorized forms and instructions for nongovernmental organizations.

Nongovernmental organizations shall use application forms and instructions prescribed by the granting agency, except that the facesheet of such applications shall be standard form 424 for grants under programs covered by Attachment A. part I, of OMB Circular No. A-95.

Subpart O—Property

GENERAL

§ 74.130 Scope and applicability of this subpart.

(a) Except as explained in paragraphs (c), (d), and (e) of this section this subpart applies to real property, equipment, and supplies acquired with grant support. To be considered acquired with grant support, some or all of the property's acquisition cost must be a direct cost under the grant, a subgrant, or a cost-type contract and must be either borne by grant funds or counted toward satisfying a grant cost-sharing or matching requirement.

(b) This subpart also deals with inventions, patents, and copyrights arising out of activities assisted by a grant or subgrant.

(c) This subpart does not apply to—

(1) Property for which only depreciation or use allowances are charged;

(2) Property donated entirely as a third-party in-kind contribution (as defined in § 74.51); or

(3) Equipment or supplies acquired primarily for sale or rental rather than for use.

(d) Equipment or supplies acquired by a contractor under its contract are not subject to this subpart if, by the terms of the contract, title to the property vests in the contractor or another third party.

(e) For research grants that are subject to an institutional cost-sharing agreement (see § 74.50(b)), real property, equipment, and supplies shall be subject to this subpart only if at least some part of the acquisition cost is borne as a direct cost by Federal grant funds.

[45 FR 22576, Apr. 3, 1980, as amended at 47 FR 53013, Nov. 24, 1982]

§ 74.131 Prohibition against additional requirements.

Recipients may follow their own property management policies and procedures: *Provided*, They observe the requirements of this subpart. Awarding parties may not impose on recipients property requirements (including property reporting requirements) not authorize by this subpart, unless specifically required by Federal statutes or Executive orders.

§ 74.132 Definitions.

As used in this subpart:

"*Acquisition*" of property includes purchase, construction, or fabrication of property, but does not include rental of property or alterations and renovations of real property.

"*Acquisition cost*" of an item of purchased equipment means the net invoice price of the equipment, including the cost of modifications, attachments, accessories, or auxiliary apparatus necessary to make the equipment usable for the purpose for which it was acquired. Other charges such as the cost of installation, transportation, taxes, duty or protective in-transit insurance shall be included in or excluded from the unit acquisition cost in accordance with the regular accounting practices of the organization purchasing the equipment. If the item is acquired by trading in another item and paying an additional amount, "acquisition cost" means the amount received for trade-in plus the additional outlay.

"*Amount received for trade-in*" of an item of equipment traded in for replacement equipment means the amount that would have been paid for the replacement equipment without a trade-in minus the amount paid with the trade-in. The term refers to the actual difference, not necessarily the trade-in value shown on an invoice.

"*Equipment*" means an article of tangible personal property that has a useful life of more than two years and an acquisition cost of $500 or more. Any recipient may use its own definition of equipment if its definition would at least include all items of equipment as defined here.

"*Personal property*" means property of any kind except real property. It may be tangible—having physical existence, or intangible--having no physical existence, such as patents, inventions, and copyrights.

"*Real property*" means land, including land improvements, structures and appurtenances thereto, but excluding movable machinery and equipment.

"*Replacement equipment*" means property acquired to take the place of other equipment. To qualify as replacement equipment, it must serve the same function as the equipment replaced and must be of the same nature or character, although not necessarily the same model, grade, or quality.

"*Supplies*" means all tangible personal property other than equipment.

[45 FR 22576, Apr. 3, 1980, as amended at 46 FR 30501, June 9, 1981]

§ 74.133 Title to real property, equipment, and supplies.

Subject to the obligations and conditions set forth in this subpart, title to real property, equipment, and supplies acquired under a grant or subgrant shall vest, upon acquisition, in the grantee or subgrantee respectively.

REAL PROPERTY

§ 74.134 Real property.

Except as otherwise provided by Federal statutes, real property to which this subpart applies shall be subject to the following requirements, in addition to any other requirements imposed by the terms of the grant:

(a) *Use.* The property shall be used for the originally authorized purpose as long as needed for that purpose. When no longer so needed, approval of the granting agency may be requested to use the property for other purposes. Use for other purposes shall be limited to:

(1) Projects or programs supported by other Federal grants or assistance agreements.

(2) Activities not supported by other Federal grants or assistance agreements but having, nevertheless, purposes consistent with those of the legislation under which the original grant was made.

(b) *Transfer of title.* Approval may be requested from the granting agency to transfer title to an eligible third party for continued use for authorized purposes in accordance with paragraph (a) of this section. If approval is permissable under Federal statutes and is given, the terms of the transfer shall provide that the transferee shall assume all the rights and obligations of the transferor set forth in this subpart or in other terms of the grant or subgrant.

(c) *Disposition.* When the real property is no longer to be used as provided in paragraphs (a) and (b) of this section, the disposition instructions of the granting agency shall be followed. Those instructions will provide for one of the following alternatives:

(1) The property shall be sold and the Federal Government shall be paid an amount computed by multiplying the Federal share of the property (see § 74.142) times the proceeds from sale (after deducting actual and reasonable selling and fix-up expenses, if any, from the sales proceeds). Proper sales procedures shall be used that provide for competition to the extent practicable and result in the highest possible return.

(2) The recipient shall have the option either of selling the property in accordance with paragraph (c)(1) of this section or of retaining title. If title is retained, the Federal Government shall be paid an amount computed by multiplying the market value of the property by the Federal share of the property.

(3) The recipient shall transfer the title to either the Federal Government or an eligible non-Federal party named by the granting agency. The grantee shall be entitled to be paid an amount computed by multiplying the market value of the property by the non-Federal share of the property. If the property belonged to a subgrantee, see § 74.143 for subgrantee's share.

EQUIPMENT AND SUPPLIES

§ 74.135 Exemptions for equipment and supplies subject to certain statutes.

(a) Some Federal statutes, in certain circumstances, permit title to equipment or supplies acquired with grant funds to vest in the recipient without further obligation to the Federal Government or on such terms and conditions as deemed appropriate. An example of such a statute is the Federal Grant and Cooperative Agreement Act of 1977, Pub. L. 95-224, which provides this authority for equipment and supplies purchased with the funds of grants (and Federal contracts and cooperative agreements) for the conduct of basic or applied scientific research at nonprofit institutions of higher education or at nonprofit organizations whose primary purpose is the conduct of scientific research.

(b) If equipment is subject to a statute of the kind described in paragraph (a) of this section, it shall be exempt from the requirements in the remaining sections of this subpart. However, an item of such equipment having a unit acquisition cost of $1,000 or more shall be subject to § 74.136, concerning rights to require transfer, and, while subject to such a right, to the rules on replacement in § 74.138.

(c) If supplies are subject to a statute of the kind described in paragraph (a) of this section, they shall be exempt from all provisions of the remainder of this subpart which would otherwise apply.

§ 74.136 Rights to require transfer of equipment.

(a) *HHS right.* For items of equipment having a unit acquisition cost of $1,000 or more, the granting agency shall have the right to require transfer of the equipment (including title) to the Federal Government or to an eligible non-Federal party named by the granting agency. This right will normally be exercised by HHS granting agencies only if the project or program for which the equipment was acquired is transferred from one grantee to another. The right shall be subject to the following conditions:

(1) In order for the granting agency to exercise the right, a specific notice that it is exercising the right or considering doing so must be issued no later than the 120th day after the end of HHS grant support for the project or program for which the equipment was acquired. Furthermore:

(i) If the equipment is eligible for the exemptions in § 74.135 and ceases to be needed for the project or program for which it was acquired while the project or program is still being performed by the recipient, the notice must have been received by the grantee while the equipment was still needed for that project or program.

(ii) If the equipment is not eligible for those exemptions, the notice must have been received by the grantee before other permissible disposition of the equipment took place in accordance with § 74.139.

(2) If the right is exercised, the grantee shall be entitled to be paid any reasonable, resulting shipping or storage costs incurred, plus an amount computed by multiplying the market value of the equipment by the non-Federal share of the equipment. (See §§ 74.142 and 74.143.)

(b) *Right of parties awarding subgrants.* When a grantee awards a subgrant, it may reserve for itself a right similar to that in paragraph (a) of this section for items of equipment having a unit acquisition cost of $1,000 or more which are acquired under that subgrant. Without the approval of the granting agency, the right may be exercised only if the project or program for which the equipment was acquired is transferred to another subgrantee and only for the purpose of transferring the equipment to the new subgrantee for continued use in the project or program.

(c) *Equipment lists.* If at any time an awarding party is considering exercising its right to require transfer of equipment, it may require the recipient to furnish it a listing of all items of equipment that are subject to the right. This will enable the awarding party to determine which items, if any, should be transferred.

§ 74.137 Use of equipment.

(a) *Basic rule.* Equipment which has not been transferred under § 74.136 shall be used by the recipient in the project or program for which it was acquired as long as needed, whether or not the project or program continues to be supported by Federal funds. When no longer needed for the original project or program, the recipient shall use the equipment, if needed, in other projects or programs currently or previously sponsored by the Federal Government, in the following order of priority:

(1) Projects or programs currently or previously sponsored by the same granting agency.

(2) Projects or programs currently or previously sponsored by other Federal agencies.

(b) *Shared use.* If equipment is being used less than full time in the project or program for which it was originally acquired, the recipient shall make it available for use in other projects or programs currently or previously sponsored by the Federal Government: *Provided,* Such other use will not interfere with the work on the original project or program. First preference for such other use shall be given to other projects or programs sponsored by the same granting agency.

(c) *Use by other recipients.* When the recipient can no longer use the equipment as required by paragraph (a) of this section, it may voluntarily make the equipment available for use on projects or programs currently or previously sponsored by the Federal Government which the recipient is supporting through subgrants or through non-Federal grants. If the recipient is a subgrantee, it may also voluntarily make the equipment available for use on projects or programs currently or previously sponsored by the Federal Government which are being conducted or supported by the grantee.

(d) *Other uses.* Unless the granting agency provides otherwise, while equipment is being used as described in the preceding paragraphs of this section, it may also be used part time for other purposes. However, use as described in those paragraphs shall be given priority over other uses.

§ 74.138 Replacement of equipment.

(a) Equipment may be exchanged for replacement equipment if needed. The replacement may take place either through trade-in or through sale and application of the proceeds to the acquisition cost of the replacement equipment. In either case, the transaction must be one which a prudent person would make in like circumstances.

(b) If an additional outlay to acquire the replacement equipment is charged as a direct cost to either Federal funds or required cost-sharing or matching under a Federal award, the replacement equipment shall be subject to whatever property requirements or exemptions are applicable to that award. If the award is a grant from HHS, the full acquisition cost of the replacement equipment shall determine which provisions of this subpart apply.

(c) For any replacement not covered by paragraph (b) of this section, the provisions of this subpart applicable to the equipment replaced shall carry over to the replacement equipment. However, none of the provisions of this subpart shall carry over if (1) the Federal share of the equipment replaced was 10 percent or less or (2) the product of that share times the amount received for trade-in or sale is $100 or less.

§ 74.139 Disposition of equipment.

When original or replacement equipment is no longer to be used in projects or programs currently or previously sponsored by the Federal Government, disposition of the equipment shall be made as follows:

(a) ***Equipment with a unit acquisition cost of less than $1,000 and equipment with no further use value.*** The equipment may be retained, sold, or otherwise disposed of, with no further obligation to the Federal Government.

(b) *All other equipment.* (1) The equipment may be retained or sold, and the Federal Government shall have a right to an amount calculated by multiplying the current market value or the proceeds from sale by the Federal share of the equipment (see § 74.142). If part of the Federal share in the equipment came from an award under which the exemptions in § 74.135 were applicable, the amount due shall be reduced pro rata. In any case, if the equipment is sold, $100 or 10 percent of the total sales proceeds, whichever is greater, may be deducted and retained from the amount otherwise due for selling and handling expenses.

(2) If the grantee's project or program for which or under which the equipment was acquired is still receiving grant support from the same Federal program and if the granting agency approves, the net amount due may be used for allowable costs of that project or program. Otherwise, the net amount must be remitted to the granting agency by check.

§ 74.140 Equipment management requirements.

Procedures for managing equipment (including replacement equipment) until transfer, replacement, or disposition takes place shall, as a minimum, meet the following requirements:

(a) Property records shall be maintained accurately. (Retention and access requirements for these records are explained in Subpart D of this part.) For each item of equipment, the records shall include:

(1) A description of the equipment, including manufacturer's model number, if any.

(2) An identification number, such as the manufacturer's serial number.

(3) Identification of the grant under which the recipient acquired the equipment.

(4) The information needed to calculate the Federal share of the equipment. (See § 74.142.)

(5) Acquisition date and unit acquisition cost.

(6) Location, use, and condition of the equipment and the date the information was reported.

(7) All pertinent information on the ultimate transfer, replacement, or disposition of the equipment.

(b) A physical inventory of equipment shall be taken and the results reconciled with the property records at least once every 2 years to verify the existence, current utilization, and continued need for the equipment. A statistical sampling basis is acceptable. Any differences between quantities determined by the physical inspection and those shown in the accounting records shall be investigated to determine the causes of the differences.

(c) A control system shall be in effect to insure adequate safeguards to prevent loss, damage, or theft of the equipment. Any loss, damage, or theft of equipment shall be investigated and fully documented.

(d) Adequate maintenance procedures shall be implemented to keep the equipment in good condition.

(e) Where equipment is to be sold and the Federal Government is to have a right to part or all of the proceeds, selling procedures shall be established which will provide for competition to the extent practicable and result in the highest possible return.

§ 74.141 Unused supplies.

(a) This section applies to supplies which have not yet been put to use in the project or program for which they were acquired when the grant or subgrant under which they were acquired expires or is terminated.

(b) If the unused supplies exceed $1,000 in total aggregate fair market value and are not needed for any project or program currently or previously funded by the Federal Government, the recipient may either retain or sell the supplies, and must credit the grant as follows:

(1) *Retained supplies.* The credit is computed by multiplying the Federal share of the supplies times their current market value.

(2) *Sold supplies.* The credit is computed by multiplying the Federal share of the supplies times the proceeds from sale. However, the recipient may reduce the credit by 10% of the sales proceeds, for selling and handling expenses.

(c) For possible exemptions from this section, see § 74.135.

[46 FR 30501, June 9, 1981]

FEDERAL SHARE OF REAL PROPERTY, EQUIPMENT, AND SUPPLIES

§ 74.142 Federal share of property.

Several sections of this subpart require a determination of the Federal (or non-Federal) share of real property, equipment, or supplies. In making such a determination, the following principles shall be observed:

(a) *General.* (1) Except as explained in the succeeding paragraphs of this section, the Federal share of the property shall be the same percentage as the Federal share of the acquiring party's total costs under the grant during the grant or subgrant year (or other funding period) to which the acquisition cost of the property was charged. For this purpose, "costs under the grant" means allowable costs which are either borne by the grant or counted towards satisfying a cost-sharing or matching requirement of the grant. Only costs are to be counted—not the value of third-party in-kind contributions. Moreover, if the property was acquired by a grantee that awarded subgrants, costs incurred by its subgrantees shall be included only to the extent borne by the subgrants. (For example, if a subgrantee incurred $200,000 of project costs, of which $150,000 was borne by the subgrant, only the $150,000 shall be included in the grantee's costs.)

(2) If the property is acquired by a subgrantee, the Federal share of the subgrantee's costs under the grant and hence of the property shall be calculated by multiplying the Federal share of the grantee's costs by the latter's share of the subgrantee's costs. For example, if the Federal share of a grantee's costs is 50 percent and the subgrant bears only 50 percent of a subgrantee's costs, then the Federal

share of that subgrantee's costs (and of the property acquired by that subgrantee) is 25 percent.

(b) *Property acquired only partly under a grant.* (1) Sometimes only a part of the acquisition cost of an item of property is borne as a direct cost by the grant or counted as a direct cost towards a cost-sharing or matching requirement. The remainder might, for example, represent voluntary cost sharing or matching, or it might be charged to a different activity. Occasionally, the amount paid for the property is only a part of its value, and the remainder is donated as an in-kind contribution by the party that provided the property.

(2) To calculate the Federal share of such property, first determine the Federal share of the acquiring party's total costs under the grant, as explained in the paragraph (a) of this section. Then multiply that share by the percentage of the property's acquisition cost (or its market value, if the item was partly donated) which was borne as a direct cost by the grant or counted as a direct cost towards a cost-sharing or matching requirement.

(c) *Replacement equipment.* The Federal share of replacement equipment shall be calculated as follows:

(1) *Step 1.* Determine the Federal share (percentage) of the equipment replaced.

(2) *Step 2.* Determine the percentage of the replacement equipment's cost that was covered by the amount received for trade-in or the sales proceeds from the equipment replaced.

(3) *Step 3.* Multiply the step 1 percentage by the step 2 percentage.

(4) *Step 4.* If an additional outlay for the replacement equipment was charged as a direct cost either to HHS grant funds or to required cost-sharing or matching funds, calculate the Federal share attributable to that additional outlay as explained in paragraph (b)(2) of this section. Add that additional percentage to the step 3 percentage.

(d) *Institutional cost-sharing agreements.* If a grant is subject to an institutional cost-sharing agreement (see § 74.130(e)), the Federal share of property acquired under the grant shall be calculated as though there were no cost-sharing requirement applicable to the grant (that is, as if all the grantee's cost sharing were voluntary).

§ 74.143 Subgrantee's share of market value or sales proceeds.

Where this subpart requires a sharing of the market value or sales proceeds of property acquired under a subgrant, the non-Federal share shall be proportionally divided between the grantee and the subgrantee. The subgrantee shall be entitled to the amount it would have received or retained if the award to it had been made directly by the Federal Government. The remainder of the non-Federal share shall belong to the grantee.

INTANGIBLE PERSONAL PROPERTY

§ 74.144 Inventions and patents.

HHS's regulations on inventions and patents arising out of activities assisted by a grant are set forth in Parts 6 and 8 of this title.

§ 74.145 Copyrights.

(a) *Works under grants.* Unless otherwise provided by the terms of the grant, when copyrightable material is developed in the course of or under a grant, the grantee is free to copyright the material or permit others to do so.

(b) *Works under subgrants.* Unless otherwise provided by the terms of the grant or subgrant, when copyrightable material is developed in the course of or under a subgrant, the subgrantee is free to copyright the material or permit others to do so.

(c) *HHS rights.* If any copyrightable material is developed in the course of or under a HHS grant or subgrant, HHS shall have a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use, and to authorize others to use, the work for Federal Government purposes. A grantee awarding a subgrant may reserve a similar right for itself with respect to copyrightable material developed under that subgrant.

(d) *Exemption of student-developed works.* HHS awards training grants and other kinds of grants under which individuals are provided stipends or other financial assistance for the primary purpose of aiding them to further their education or training. Except as provided by the terms of the grant, copyrightable material developed by an individual or group of individuals in the course of education or training pursued with such assistance shall not be subject to the HHS right described in paragraph (c) of this section, unless the development of the material also receives other forms of support under the same or another HHS grant (such as a research grant).

Subpart P—Procurements by Grantees and Subgrantees

SOURCE: 45 FR 37667, June 3, 1980, unless otherwise noted.

§ 74.160 What procurements are subject to this subpart?

(a) This subpart applies to recipient procurements of supplies, equipment, and services (including construction).

(b) This subpart applies if any part of the cost of the property or service being procured by a recipient is treated as a direct cost under a grant or subgrant and is either borne by grant funds or counted toward satisfying a cost-sharing or matching requirement of the Federal grant. However, for research grants subject to an institutional cost-sharing agreement (see § 74.50(b)), this subpart applies only if some part of the cost is borne by grant funds.

(c) This subpart does not apply to the acquisition of property or services by one government from another government or by one agency or instrumentality of a government from another agency or instrumentality of the same or another government.[1]

§ 74.161 What rules govern the procurements?

For procurements by governmental recipients, awarding parties and recipients shall comply with Attachment O, "Procurement Standards," of OMB Circular A-102. For procurements by nongovernmental recipients, awarding parties and recipients shall comply with Attachment O, "Procurement Standards," of OMB Circular A-110. The versions of the attachments that apply are those in effect on October 1, 1979. The texts of those versions are in Appendices G and H of this part.

§ 74.162 Must requests for OMB authorizations go through HHS's Office of Procurement, Assistance and Logistics (OPAL)?

Requests for the Office of Federal Procurement Policy approval or authorizations referred to in paragraphs 1.b, 1.c, and 14.j of the OMB Circular A-102 attachment must be submitted, through appropriate HHS granting agency channels, to OPAL. If OPAL concurs in the request, OPAL sends it to the Office of Federal Procurement Policy of OMB.

[47 FR 53013, Nov. 24, 1982]

§ 74.163 How do the rules apply to subgrants?

(a) The Attachments O of the OMB circulars apply to procurements under subgrants as well as grants, although written, for the most part, in terms of grants. Except as explained in paragraphs (b) and (c) of this section, in the case of a subgrant, text that applies to a Federal agency is to be construed as applying to the grantee awarding the subgrant and text that applies to a grantee is to be construed as applying to the recipient of the subgrant.

(b) In section 4 and paragraphs 14.d through 14.i of Attachment O of OMB Circular A-102 and in paragraphs 4.e through 4.j of Attachment O of OMB Circular A-110, the references to Federal agencies apply to Federal agencies even in the case of a subgrant.

(c) In paragraph 2.a of Attachment O of OMB Circular A-102, the reference to a Federal concern is to be construed, in the case of a subgrant, as referring to a concern of either the Federal Government or the grantee awarding the subgrant.

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[1] Instrumentalities of a government include government institutions of higher education and government hospitals. However, those institutions and hospitals are not considered governmental organizations for the other purposes of this subpart. (See paragraph (c) of § 74.4, "Applicability of this part.")

§ 74.164 What clarifications are needed for the rule on access to contractor records?

The Attachments O require recipients to include in specified kinds of contracts a provision for access to the contractor's records by the recipient and the Federal Government. The following applies to the provision:

(a) The provision must require the contractor to place the same provision in any subcontract which would have to have the provision were it awarded directly by the recipient.

(b) The provision must require retention of records for three years after final payment is made under the contract or subcontract and all pending matters are closed. The provision must also require that, if an audit, litigation, or other action involving the records is started before the end of the three-year period, the records must be retained until all issues arising out of the action are resolved or until the end of the three-year period, whichever is later.

(c) In contracts and subcontracts under a subgrant, the provision must require that access to the records be provided to the grantee as well as the subgrantee and the Federal Government.

[45 FR 37667, June 3, 1980; 45 FR 38380, June 9, 1980]

Subpart Q—Cost Principles

§ 74.170 Basic policy; scope of subpart.

Grant funds may be used only for allowable costs of the activities for which the grant was awarded. This subpart identifies the principles to be used in determining allowable costs. The principles apply to grant-support activities conducted by grantees as well as by subgrantees and cost-type contractors (and subcontractors) under grants.

[45 FR 34273, May 22, 1980]

§ 74.171 Governments.

(a) The principles to be used in determining the allowable costs of activities conducted by governments are contained in OMB Circular No. A-87, including any amendments to the Circular published in the FEDERAL REGISTER by OMB. A copy of this Circular may be obtained from the Division of Cost Allocation in any HHS Regional Office.

(b) Unless otherwise prescribed by OMB, future amendments to the Circular shall apply as of the start of a government's first fiscal year beginning after the amendment is published in the FEDERAL REGISTER.

[45 FR 34273, May 22, 1980, as amended at 47 FR 53013, Nov. 24, 1982]

§ 74.172 Institutions of higher education.

(a) The principles to be used in determining the allowable costs of activities conducted by institutions of higher education (other than for profit institutions) are contained in OMB Circular No. A-21, including any amendments to the Circular published in the FEDERAL REGISTER by OMB. A copy of this Circular may be obtained from the Division of Cost Allocation in any HHS Regional Office.

(b) Unless otherwise prescribed by OMB, future amendments to the Circular shall apply as of the start of an institution's first fiscal year beginning after the amendment is published in the FEDERAL REGISTER.

[45 FR 34273, May 22, 1980]

§ 74.173 Hospitals.

(a) *Research and development.* The principles for determining the allowable costs of research and development work performed by hospitals are in Appendix E to this part.

(b) *Other activities.* Appendix E to this part shall be used as a guide for determining the allowable costs of other activities conducted by hospitals.

§ 74.174 Other nonprofit organizations.

(a) Except as provided in paragraph (c) of this section, the principles to be used in determining allowable costs of activities conducted by nonprofit organizations (other than governments, institutions of higher education, and hospitals) are contained in OMB Circular A-122, , including any amendments to the Circular published in the FEDERAL REGISTER by OMB. A copy of this Circular may be obtained from the Division of Cost Allocation in any HHS Regional Office. Unless otherwise prescribed by OMB, amendments to the Circular shall apply as of the start of an organization's first fiscal year beginning after the amendment is published in the FEDERAL REGISTER.

(b) OMB Circular A-122 does not cover the treatment of bid and proposal costs or independent research and development costs. The following rules apply to these costs for nonprofit organizations subject to the Circular:

(1) *Bid and proposal costs.* Bid and proposal costs are the immediate costs of preparing bids, proposals, and applications for potential Federal and non-Federal grants, contracts, and agreements, including the development of scientific, cost, and other data needed to support the bids, proposals and applications. Bid and proposal costs of the current accounting period are allowable as indirect costs. Bid and proposal costs of past accounting periods are unallowable in the current period. However, if the organization's established practice is to treat these costs by some other method, they may be accepted if they are found to be reasonable and equitable. Bid and proposal costs do not include independent research and development costs covered by paragraph (b)(2) of this section, or preaward costs covered by Attachment B, Paragraph 33, of OMB Circular A-122.

(2) *Independent research and development costs.* Independent research and development is research and development conducted by an organization which is not sponsored by Federal or non-Federal grants, contracts, or other agreements. Independent research and development shall be allocated its proportionate share of indirect costs on the same basis as the allocation of indirect costs to sponsored research and development. The costs of independent research and development, including its proportionate share of indirect costs, are unallowable.

(c) The principles to be used in determining allowable costs of activities conducted by the nonprofit organizations listed in Attachment C to OMB Circular A-122 are contained in Subpart 1-15.2 of the Federal Procurement Regulations (41 CFR 1-15.2), except that the costs of independent research and development, including its proportionate share of indirect costs, are unallowable.

[46 FR 30502, June 9, 1981]

§ 74.175 For-profit organizations other than for-profit hospitals.

(a) The principles to be used in determining the allowable costs of activities conducted by for-profit organizations (other than for-profit hospitals) are contained in the Federal Procurement Regulations at 41 CFR Subpart 1-15.2. *Exception:* Independent research and development costs (including the indirect costs allocable to them) are unallowable. Independent research and development are defined in the Federal Procurement Regulations at 41 CFR 1-15.205-35.

(b) For hospitals, see § 74.173.

[47 FR 53013, Nov. 24, 1982]

§ 74.176 Subgrants and cost-type contracts.

The cost principles applicable to a subgrantee or cost-type contractor under an HHS grant will not necessarily be the same as those applicable to the grantee. For example, where a State government awards a subgrant or cost-type contract to an institution of higher education, OMB Circular No. A-21 will apply to the costs incurred by the institution of higher education even though OMB Circular No A-87 will apply to the costs incurred by the State.

[47 FR 53013, Nov. 24, 1982]

§ 74.177 Costs allowable with approval.

Each set of cost principles identifies certain costs that, in order to be allowable, must be approved by the granting agency. Other costs do not require approval. The following procedures govern approval of these costs.

(a) When costs are treated as indirect costs (or are allocated pursuant to a government-wide cost allocation plan), acceptance of the costs as part of the indirect cost rate or cost allocation plan shall constitute approval.

(b)(1) When the costs are treated as direct costs, they must be approved in advance by the awarding party.

(2) If the costs are specified in the budget, approval of the budget shall constitute approval of the costs.

(3) If the costs are not specified in the budget, or there is no approved budget, the recipient shall obtain specific prior approval in writing from the awarding party. For this purpose the prior approval procedures of § 74.102 shall be followed, except that for formula or mandatory grants, the granting agency's written approval may be signed by any authorized official of the granting agency.

(c) The awarding party may waive or conditionally waive the requirement for its approval of the costs. Such a waiver shall apply only to the requirement for approval. If, upon audit or otherwise, it is determined that the costs do not meet other requirements or tests for allowability specified by the applicable cost principles, such as reasonableness and necessity, the costs may be disallowed.

(d) In the case of subgrants and cost-type contracts, no approval shall be given which is inconsistent with the purpose or the terms of the Federal grant.

[45 FR 22576, Apr. 3, 1980. Redesignated at 47 FR 53013, Nov. 24, 1982]

Subparts R—S [Reserved]

Subpart T—Miscellaneous

§ 74.304 Final decisions in disputes.

(a) Granting agencies and other Departmental components attempt to promptly issue final decisions in disputes and in other matters affecting the interests of grantees. However, they do not issue a final decision adverse to the grantee until it is clear that the matter cannot be resolved informally through further exchange of information and views.

(b) Under various HHS statutes or regulations, grantees have the right to appeal from, or to have a hearing on, certain final decisions by Departmental components. (See, for example, Subpart D of 42 CFR Part 50 and 45 CFR Parts 16 and 75.) Paragraphs (c) and (d) of this section set forth the standards the Department expects its components to meet in stating a final decision covered by any of the statutes or regulations.

(c) The decision is brief but contains—

(1) A complete statement of the background and basis of the component's decision, including reference to the pertinent statutes, regulations, or other governing documents; and

(2) Enough information to enable the grantee and any reviewer to understand the issues and the position of the HHS component.

(d) The following or similar language (consistent with the terminology of the applicable statutes or regulations) appears at the end of the decision: "This is the final decision of the [title of grants officer or other official responsible for the decision]. It shall be the final decision of the Department unless, within 30 days after receiving this decision, you deliver or mail (you should use registered or certified mail to establish the date) a written notice of appeal to [name and address of appropriate contact; e.g., the Departmental Grant Appeals Board, Department of Health and Human Services, Washington, DC 20201]. You shall attach to the notice a copy of this decision, note that you intend an appeal, state the amount in dispute, and briefly state why you think that this decision is wrong. You will be notified of further procedures."

(e) If a decision does not contain the statement, information, and language described in paragraphs (c) and (d) of this section, the decision is not necessarily the granting agency's final decision in the matter. The grantee should notify the granting agency that it wishes a formal final decision following any further exchange of views or information that might help resolve the matter informally.

[46 FR 43822, Aug. 31, 1981]

Subparts U—Z [Reserved]

Subpart AA—Special Provisions for Grants and Subgrants to For-Profit Organizations

SOURCE: 47 FR 53014, Nov. 24, 1982, unless otherwise noted.

§ 74.701 Scope of subpart.

(a) This subpart contains provisions that apply to grants and subgrants to for-profit organizations. These provisions are in addition to other applicable portions of this part, or they make exceptions for awards to for-profit organizations from other provisions of this part.

(b) This subpart also draws attention to, or discusses, provisions elsewhere in this part that need special emphasis or clarification with respect to awards to for-profit organizations.

§ 74.705 Prohibition against profit.

Attention is directed to § 74.170, which provides, in effect, that no grant funds may be paid as profit to any recipient of a grant or subgrant, even if the recipient is a for-profit organization. Profit is any amount in excess of allowable direct and indirect costs of the recipient.

§ 74.710 Real property, equipment, and supplies.

(a) *Scope.* (1) This section applies to real property, equipment, and supplies which, in accordance with § 74.130, would be subject to Subpart O of this part but is acquired under a grant or subgrant to a for-profit organization.

(2) A grantee that is not a for-profit organization may take title to property acquired under a subgrant to a for-profit organization. If so, the property will be considered as acquired by the grantee under its grant, and this section will not apply to the property.

(b) *Applicable rules.* (1) Property subject to this section is exempt from Subpart O of this part. Instead, the clause entitled "Government Property" in 41 CFR 1-7.203-21(a) is deemed to be in every grant or subgrant to a for-profit organization, and the provisions in that clause that apply to property acquired for the Government apply to property subject to this section. For this purpose, the terms "contract" and its derivatives in that clause are considered to refer to the grant or subgrant under which the property is acquired, "subcontract" and its derivatives to refer to any subaward under that grant or subgrant, and "contracting Officer" to refer to the HHS grants officer.

(2) Records subject to the Government Property clause are exempt from Subpart D of this part.

(c) *Approval for acquisition.* A recipient shall not acquire property to be subject to this section without the prior approval of the granting agency.

§ 74.715 General program income.

The additional costs alternative described in § 74.42(e) of this part may not be applied to general program income earned by a recipient that is a for-profit organization.

§ 74.720 Cost sharing under research grants.

Under research grants to for-profit organizations, HHS does not enter into institutional cost-sharing agreements that cover all or a number of its research project grants to the grantee in the aggregate. In research grants to these organizations, HHS implements statutory requirements for cost sharing through separate cost-sharing agreements negotiated for each research project.

APPENDICES A—D TO PART 74 [RESERVED]

APPENDIX E to Part 74—PRINCIPLES FOR DETERMINING COSTS APPLICABLE TO RESEARCH AND DEVELOPMENT UNDER GRANTS AND CONTRACTS WITH HOSPITALS

I. PURPOSE AND SCOPE

A. *Objectives.* This appendix provides principles for determining the costs applicable to research and development work performed by hospitals under grants and contracts with the Department of Health and Human Services. These principles are confined to the subject of cost determination and make no attempt to identify the circumstances or dictate the extent of hospital participation in the financing of a particular research or development project. The principles are designed to provide recognition of the full allocated costs of such research work under generally accepted accounting principles. These principles will be applicable to both proprietary and non-profit hospitals. No provision for profit or other increment above cost is provided for in these principles. However, this is not to be interpreted as precluding a negotiated fee between contracting parties when a fee is appropriate.

B. *Policy guides.* The successful application of these principles requires development of mutual understanding between representatives of hospitals and of the Department of Health and Human Services as to their scope, applicability and interpretation. It is recognized that:

1. The arrangements for hospital participation in the financing of a research and development project are properly subject to negotiation between the agency and the hospital concerned in accordance with such Government-wide criteria as may be applicable.

2. Each hospital, possessing its own unique combination of staff, facilities and experience, should be encouraged to conduct research in a manner consonant with its own institutional philosophies and objectives.

3. Each hospital in the fulfillment of its contractual obligations should be expected to employ sound management practices.

4. The application of the principles established herein shall be in conformance with the generally accepted accounting practices of hospitals.

5. Hospitals receive reimbursements from the Federal Government for differing types of services under various programs such as support of Research and Development (including discrete clinical centers) Health Services Projects, Medicare, etc. It is essential that consistent procedures for determining reimbursable costs for similar services be employed without regard to program differences. Therefore, both the direct and indirect costs of research programs must be identified as a cost center(s) for the cost finding and step-down requirements of the Medicare program, or in its absence the Medicaid program.

C. *Application.* All operating agencies within the Department of Health and Human Services that sponsor research and development work in hospitals will apply these principles and related policy guides in determining the costs incurred for such work under grants and cost-reimbursement type contracts and subcontracts. These principles will also be used as a guide in the pricing of fixed-price contracts and subcontracts.

II. DEFINITIONS OF TERMS

A. "Organized research" means all research activities of a hospital that may be identified whether the support for such research is from a federal, non-federal or internal source.

B. "Departmental research" means research activities that are not separately budgeted and accounted for. Such work, which includes all research activities not encompassed under the term organized research, is regarded for purposes of this document as a part of the patient care activities of the hospital.

C. "Research agreement" means any valid arrangement to perform federally-sponsored research or development including grants, cost-reimbursement type contracts, cost-reimbursement type subcontracts, and fixed-price contracts and subcontracts.

D. "Instruction and training" means the formal or informal programs of educating and training technical and professional health services personnel, primarily medical and nursing training. This activity, if separately budgeted or identifiable with specific costs, should be considered as a cost objective for purposes of indirect cost allocations and the development of patient care costs.

E. "Other hospital activities" means all organized activities of a hospital not immediately related to the patient care, research, and instructional and training functions which produce identifiable revenue from the performance of these activities. If a non-related activity does not produce identifiable revenue, it may be necessary to allocate this expense using an appropriate basis. In such a case, the activity may be included as an allocable cost (See paragraph III D below.) Also included under this definition is any category of cost treated as "Unallowable," provided such category of cost identifies a function or activity to which a portion of the institution's indirect cost (as defined in paragraph V. A.) are properly allocable.

F. "Patient care" means those departments or cost centers which render routine or ancillary services to in-patients and/or out-patients. As used in paragraph IX B.23, it means the cost of these services applicable to patients involved in research programs.

G. "Allocation" means the process by which the indirect costs are assigned as between:

1. Organized research,

2. Patient care including departmental research.

3. Instruction and training, and

4. Other hospital activities.

H. "Cost center" means an identifiable department or area (including research) within the hospital which has been assigned an account number in the hospital accounting system for the purpose of accumulating expense by department or area.

I. "Cost finding" is the process of recasting the data derived from the accounts ordinarily kept by a hospital to ascertain costs of the various types of services rendered. It is the determination of direct costs by specific identification and the proration of indirect costs by allocation.

J. "Step down" is a cost finding method that recognizes that services rendered by certain nonrevenue-producing departments or centers are utilized by certain other nonrevenue producing centers as well as by the revenue-producing centers. All costs of nonrevenue-producing centers are allocated to all centers which they serve, regardless of whether or not these centers produce revenue. Following the apportionment of the cost of the nonrevenue-producing center, that center will be considered closed and no further costs are apportioned to that center.

K. "Scatter bed" is a bed assigned to a research patient based on availability. Research patients occupying these beds are not physically segregated from nonresearch patients occupying beds. Scatter beds are geographically dispersed among all the beds available for use in the hospital. There are no special features attendant to a scatter bed that distinguishes it from others that could just as well have been occupied.

L. "Discrete bed" is a bed or beds that have been set aside for occupancy by research patients and are physically segregated from other hospital beds in an environment that permits an easily ascertainable allocation of costs associated with the space they occupy and the services they generate.

III. BASIC CONSIDERATIONS

A. *Composition of total costs.* The cost of a research agreement is comprised of the allowable direct costs incident to its performance plus the allocable portion of the allowable indirect costs of the hospital less applicable credits. (See paragraph III-E.)

B. *Factors affecting allowability of costs.* The tests of allowability of costs under these principles are:

1. They must be reasonable.

2. They must be assigned to research agreements under the standards and methods provided herein.

3. They must be accorded consistent treatment through application of those generally accepted accounting principles appropriate to the circumstances (See paragraph I-E.5.) and

4. They must conform to any limitations or exclusions set forth in these principles or in the research agreement as to types or amounts of cost items.

C. *Reasonable costs.* A cost may be considered reasonable if the nature of the goods or services acquired or applied, and the amount involved therefor reflect the action that a prudent person would have taken under the circumstances prevailing at the time the decision to incur the cost was made. Major considerations involved in the determination of the reasonableness of a cost are:

1. Whether or not the cost is of a type generally recognized as necessary for the operation of the hospital or the performance of the research agreement,

2. The restraints or requirements imposed by such factors as arm's length bargaining, federal and state laws and regulations, and research agreement terms and conditions,

3. Whether or not the individuals concerned acted with due prudence in the circumstances, considering their responsibilities to the hospital, its patients, its employees, its students, the Government, and the public at large, and

4. The extent to which the actions taken with respect to the incurrence of the cost are consistent with established hospital policies and practices applicable to the work of the hospital generally, including Government research.

D. *Allocable costs.* 1. A cost is allocable to a particular cost center (i.e., a specific function, project, research agreement, department, or the like) if the goods or services involved are chargeable or assignable to such cost center in accordance with relative benefits received or other equitable relationship. Subject to the foregoing, a cost is allocable to a research agreement if it is incurred solely to advance the work under the research agreement; or it benefits both the research agreement and other work of the hospital in proportions that can be approximated through use of reasonable methods; or it is necessary to the overall operation of the hospital and, in light of the standards provided in this chapter, is deemed to be assignable in part to organized research. Where the purchase of equipment or other capital items are specifically authorized under a research agreement, the amounts thus authorized for such purchases are allocable to the research agreement regardless of the use that may subsequently be made of the equipment or other capital items involved.

2. Any costs allocable to a particular research agreement under the standards provided in these principles may not be shifted to other research agreements in order to meet deficiencies caused by overruns or other fund considerations, to avoid restrictions imposed by law or by terms of the research agreement, or for other reasons of convenience.

E. *Applicable credits.* 1. The term applicable credits refers to those receipts or negative expenditure types of transactions which operate to offset or reduce expense items that are allocable to research agreements as direct or indirect costs as outlined in paragraph V-A. Typical examples of such transactions are: purchase discounts, rebates, or allowances; recoveries or indemnities on losses; sales of scrap or incidental services; tuition; adjustments of overpayments or erroneous charges; and services rendered to patients admitted to federally funded clinical research centers, primarily for care though also participating in research protocols.

2. In some instances, the amounts received from the Federal Government to finance hospital activities or service operations should be treated as applicable credits. Specifically, the concept of netting such credit items against related expenditures should be applied by the hospital in determining the rates or amounts to be charged to government research for services rendered whenever the facilities or other resources used in providing such services have been financed directly, in whole or in part, by federal funds. Thus, where such items are provided for or benefit a particular hospital activity, i.e., patient care, research, instruction and training, or other, they should be treated as an offset to the indirect costs apportioned to that activity. Where the benefits are common to all hospital activities they should be treated as a credit to the total indirect cost pool before allocation to the various cost objectives.

IV. DIRECT COSTS

A. *General.* Direct costs are those that can be identified specifically with a particular cost center. For this purpose, the term cost center refers not only to the ultimate centers against which costs are finally lodged such as research agreements, but also to other established cost centers such as the individual accounts for recording particular objects or items of expense, and the separate account groupings designed to record the expenses incurred by individual organizational units, functions, projects and the like. In general, the administrative functions and service activities described in paragraph VI are identifiable as separate cost centers, and the expenses associated with such centers become eligible in due course for distribution as indirect costs of research agreements and other ultimate cost centers.

B. *Application to research agreements.* Identifiable benefit to the research work rather than the nature of the goods and services involved is the determining factor in distinguishing direct from indirect costs of research agreements. Typical of transactions chargeable to a research agreement as direct costs are the compensation of employees for the time or effort devoted to the performance of work under the research agreement, including related staff benefit and pension plan costs to the extent that such items are consistently accorded to all employees and treated by the hospital as direct rather than indirect costs (see paragraph V. B4b); the costs of materials consumed or expended in the performance of such work; and other items of expense incurred for the research agreement, such as extraordinary utility consumption. The cost of materials supplied from stock or services rendered by specialized facilities or other institutional service operations may be included as direct costs of research agreements provided such items are consistently treated by the institution as direct rather than indirect costs and are charged under a recognized method of costing or pricing designed to recover only the actual direct and indirect costs of such material or service and conforming to generally accepted cost accounting practices consistently followed by the institution.

V. INDIRECT COSTS

A. *General.* Indirect costs are those that have been incurred for common or joint objectives, and thus are not readily subject to treatment as direct costs of research agreements or other ultimate or revenue producing cost centers. In hospitals such costs normally are classified but not necessarily restricted to the following functional categories: Depreciation; Administrative and General (including fringe benefits if not charged directly); Operation of Plant; Maintenance of Plant; Laundry and Linen Service; Housekeeping; Dietary; Maintenance of Personnel; and Medical Records and Library.

B. *Criteria for distribution*—1. *Base period.* A base period for distribution of indirect costs is the period during which such costs are incurred and accumulated for distribution to work performed within that period. The base period normally should coincide with the fiscal year established by the hospital, but in any event the base period should be so selected as to avoid inequities in the distribution of costs.

2. *Need for cost groupings.* The overall objective of the allocation process is to distribute the indirect costs described in paragraph VI to organized research, patient care, instruction and training, and other hospital activities in reasonable proportions consistent with the nature and extent of the use of the hospital's resources by research personnel, medical staff, patients, students, and other personnel or organizations. In order to achieve this objective with reasonable precision, it may be necessary to provide for selective distribution by establishing separate groupings of cost within one or more of the functional categories of indirect costs referred to in paragraph V-A. In general, the cost groupings established within a functional category should constitute, in each case, a pool of those items of expense

that are considered to be of like character in terms of their relative contribution to (or degree of remoteness from) the particular cost centers to which distribution is appropriate. Each such pool or cost grouping should then be distributed individually to the related cost centers, using the distribution base or method most appropriate in the light of the guides set out in B3 below. While this paragraph places primary emphasis on a step-down method of indirect cost computation, paragraph VIII provides an alternate method which may be used under certain conditions.

3. *Selection of distribution method.* Actual conditions must be taken into account in selecting the method or base to be used in distributing to related cost centers the expenses assembled under each of the individual cost groups established as indicated under B2 above. Where a distribution can be made by assignment of a cost grouping directly to the area benefited, the distribution should be made in that manner. Care should be given, however, to eliminate similar or duplicative costs from any other distribution made to this area. Where the expenses under a cost grouping are more general in nature, the distribution to related cost centers should be made through use of a selected base which will produce results which are equitable to both the Government and the hospital. In general, any cost element or cost-related factor associated with the hospital's work is potentially adaptable for use as a distribution base provided:

a. It can readily be expressed in terms of dollars or other quantitative measure (total direct expenditures, direct salaries, manhours applied, square feet utilized, hours of usage, number of documents processed, population served, and the like); and

b. It is common to the related cost centers during the base period. The essential consideration in selection of the distribution base in each instance is that it be the one best suited for assigning the pool of costs to related cost centers in accord with the relative benefits derived; the traceable cause and effect relationship; or logic and reason, where neither benefit nor cause and effect relationship is determinable.

4. *General consideration on cost groupings.* The extent to which separate cost groupings and selective distribution would be appropriate at a hospital is a matter of judgment to be determined on a case-by-case basis. Typical situations which may warrant the establishment of two or more separate cost groups (based on account classification or analysis) within a functional category include but are not limited to the following:

a. Where certain items or categories of expense relate solely to one of the major divisions of the hospital (patient care, sponsored research, instruction and training, or other hospital activities) or to any two but not all, such expenses should be set aside as a separate cost grouping for direct assignment or selective distribution in accordance with the guides provided in B2 and B3 above.

b. Where any types of expense ordinarily treated as indirect cost as outlined in paragraph V-A are charged to research agreements as direct costs, the similar type expenses applicable to other activities of the institution must through separate cost grouping be excluded from the indirect costs allocable to research agreements.

c. Where it is determined that certain expenses are for the support of a service unit or facility whose output is susceptible of measurement on a workload or other quantitative basis, such expenses should be set aside as a separate cost grouping for distribution on such basis to organized research and other hospital activities.

d. Where organized activities (including identifiable segments of organized research as well as the activities cited in paragraph II-E) provide their own purchasing, personnel administration, building maintenance, or housekeeping or similar service, the distribution of such elements of indirect cost to such activities should be accomplished through cost grouping which includes only that portion of central indirect costs (such as for overall management) which are properly allocable to such activities.

e. Where the hospital elects to treat as indirect charges the costs of pension plans and other staff benefits, such costs should be set aside as a separate cost grouping for selective distribution to related cost centers, including organized research.

f. Where the hospital is affiliated with a medical school or some other institution which performs organized research on the hospital's premises, every effort should be made to establish separate cost groupings in the Administrative and General or other applicable category which will reasonably reflect the use of services and facilities by such research. (See also paragraph VII-A.3)

5. *Materiality.* Where it is determined that the use of separate cost groupings and selective distribution are necessary to produce equitable results, the number of such separate cost groupings within a functional category should be held within practical limits, after taking into consideration the materiality of the amounts involved and the degree of precision attainable through less selective methods of distribution.

C. *Administration of limitations on allowances for indirect costs.* 1. Research grants may be subject to laws and/or administrative regulations that limit the allowance for indirect costs under each such grant to a stated percentage of the direct costs allowed. Agencies that sponsor such grants will establish procedures which will assure that:

a. The terms and amount authorized in each case conform with the provisions of paragraphs III, V and IX of these principles as they apply to matters involving the consistent treatment and allowability of individual items of cost; and

b. The amount actually allowed for indirect costs under each such research grant does not exceed the maximum allowable under the limitation or the amount otherwise allowable under these principles, whichever is the smaller.

2. Where the actual allowance for indirect costs on any research grant must be restricted to the smaller of the two alternative amounts referred to in C1 above, such alternative amounts should be determined in accordance with the following guides:

a. The maximum allowable under the limitation should be established by applying the stated percentage to a direct cost base which shall include all items of expenditure authorized by the sponsoring agency for inclusion as part of the total cost for the direct benefit of the work under the grant; and

b. The amount otherwise allowable under these principles should be established by applying the current institutional indirect cost rate to those elements of direct cost which were included in the base on which the rate was computed.

3. When the maximum amount allowable under a statutory limitation or the terms of a research agreement is less than the amount otherwise allocable as indirect costs under these principles, the amount not recoverable as indirect costs under the research agreement involved may not be shifted to other research agreements.

VI. IDENTIFICATION AND ASSIGNMENT OF INDIRECT COSTS

A. *Depreciation or use charge.* 1. The expenses under this heading should include depreciation (as defined in paragraph IX-B.9a) on buildings, fixed equipment, and movable equipment, except to the extent purchased through federal funds. Where adequate records for the recording of depreciation are not available, a use charge may be substituted for depreciation (See paragraph IX-B.)

2. The expenses included in this category should be allocated to applicable cost centers in a manner consistent with the guides set forth in paragraph V-B, on a basis that gives primary emphasis to (a) space utilization with respect to depreciation on buildings and fixed equipment; and (b) specific identification of assets and their use with respect to movable equipment as it relates to patient care, organized research, instruction and training, and other hospital activities. Where such records are not sufficient for the purpose of the foregoing, reasonable estimates will suffice as a means for effecting distribution of the amounts involved.

B. *Administration and general expenses.* 1. The expenses under this heading are those that have been incurred for the administrative offices of the hospital including accounting, personnel, purchasing, information centers, telephone expense, and the like which do not relate solely to any major division of the institution, i.e., solely to patient care, organized research, instruction and training, or other hospital activities.

2. The expenses included in this category may be allocated on the basis of total expenditures exclusive of capital expenditures, or salaries and wages in situations where the results of the distribution made on this basis are deemed to be equitable both to the Government and the hospital; otherwise the distribution of Administration and General expenses should be made through use of selected bases, applied to separate cost groupings established within this category of expenses in accordance with the guides set out in paragraph V-B.

C. *Operation of plant.* 1. The expenses under this heading are those that have been incurred by a central service organization or at the departmental level for the administration, supervision, and provision of utilities (exclusive of telephone expense) and protective services to the physical plant. They include expenses incurred for such items as power plant operations, general utility costs, elevator operations, protection services, and general parking lots.

2. The expenses included in this category should be allocated to applicable cost centers in a manner consistent with the guides provided in paragraph V-B, on a basis that gives primary emphasis to space utilization. The allocations should be developed as follows:

a. Where actual space and related cost records are available or can readily be developed and maintained without significant change in the accounting practices, the amount distributed should be based on such records;

b. Where the space and related cost records maintained are not sufficient for purposes of the foregoing, a reasonable estimate of the proportion of total space assigned to the various costs centers normally will suffice as a means for effecting distribution of the amounts involved; or

c. Where it can be demonstrated that an area or volume or space basis of allocation is impractical or inequitable, other bases may be used provided consideration is given to the use of facilities by research personnel and others, including patients.

D. *Maintenance of plant.* 1. The expenses under this heading should include:

a. All salaries and wages pertaining to ordinary repair and maintenance work performed by employees on the payroll of the hospital;

b. All supplies and parts used in the ordinary repairing and maintaining of buildings and general equipment; and

c. Amounts paid to outside concerns for the ordinary repairing and maintaining of buildings and general equipment.

2. The expenses included in this category should be allocated to applicable cost centers in a manner consistent with the guides provided in paragraph V-B. on a basis that gives primary emphasis to space utilization. The allocations and apportionments should be developed as follows:

a. Where actual space and related cost records are available and can readily be developed and maintained without significant change in the accounting practices, the amount distributed should be based on such records;

b. Where the space and related cost records maintained are not sufficient for purposes of the foregoing, a reasonable estimate of the proportion of total space assigned to the various cost centers normally will suffice as a means for effecting distribution of the amounts involved; or

c. Where it can be demonstrated that an area or volume of space basis of allocation is impractical or inequitable, other basis may be used provided consideration is given to the use of facilities by research personnel and others, including patients.

E. *Laundry and linen.* 1. The expenses under this heading should include:

a. Salaries and wages of laundry department employees, seamstresses, clean linen handlers, linen delivery men, etc.;

b. Supplies used in connection with the laundry operation and all linens purchased; and

c. Amounts paid to outside concerns for purchased laundry and/or linen service.

2. The expense included in this category should be allocated to related cost centers in a manner consistent with the guides provided in paragraph V-B. on a basis that gives primary emphasis to actual pounds of linen used. The allocations should be developed as follows:

a. Where actual poundage and related cost records are available or can readily be developed and maintained without significant change in the accounting practices, the amount distributed should be based on such records;

b. Where it can be demonstrated that a poundage basis of allocation is impractical or inequitable other bases may be used provided consideration is given to the use of linen by research personnel and others, including patients.

F. *Housekeeping.* 1. The expenses under this heading should include:

a. All salaries and wages of the department head, foreman, maids, porters, janitors, wall washers, and other housekeeping employees;

b. All supplies used in carrying out the housekeeping functions; and

c. Amounts paid to outside concerns for purchased services such as window washing, insect extermination, etc.

2. The expenses included in this category should be allocated to related cost centers in a manner consistent with the guides provided in paragraph V-B. on a basis that gives primary emphasis to space actually serviced by the housekeeping department. The allocations and apportionments should be developed as follows:

a. Where actual space serviced and related cost records are available or can readily be developed and maintained without significant change in the accounting practices, the amount distributed should be based on such records;

b. Where the space serviced and related cost records maintained are not sufficient for purposes of the foregoing, a reasonable estimate of the proportion of total space assigned to the various cost centers normally will suffice as a means for effecting distribution of the amounts of housekeeping expenses involved; or

c. Where it can be demonstrated that the space serviced basis of allocation is impractical or inequitable, other bases may be used provided consideration is given to the use of housekeeping services by research personnel and others, including patients.

G. *Dietary.* 1. These expenses, as used herein, shall mean only the subsidy provided by the hospital to its employees including research personnel through its cafeteria operation. The hospital must be able to demonstrate through the use of proper cost accounting techniques that the cafeteria operates at a loss to the benefit of employees.

2. The reasonable operating loss of a subsidized cafeteria operation should be allocated to related cost centers in a manner consistent with the guides provided in paragraph V-B. on a basis that gives primary emphasis to number of employees.

H. *Maintenance (housing) of personnel.* 1. The expenses under this heading should include:

a. The salaries and wages of matrons, clerks, and other employees engaged in work in nurses' residences and other employees' quarters;

b. All supplies used in connection with the operation of such dormitories; and

c. Payments to outside agencies for the rental of houses, apartments, or rooms used by hospital personnel.

2. The expenses included in this category should be allocated to related cost centers in a manner consistent with the guides provid-

ed in paragraph V-B. on a basis that gives primary emphasis to employee utilization of housing facilities. The allocation should be developed as follows:

a. Appropriate credit should be given for all payments received from employees or otherwise to reduce the expense to be allocated;

b. A net cost per housed employee may then be computed; and

c. Allocation should be made on a departmental basis based on the number of housed employees in each respective department.

I. *Medical records and library.* 1. The expenses under this heading should include:

a. The salaries and wages of the records librarian, medical librarian, clerks, stenographers, etc.; and

b. All supplies such as medical record forms, chart covers, filing supplies, stationery, medical library books, periodicals, etc.

2. The expenses included in this category should be allocated to related cost centers in a manner consistent with the guides provided in paragraph V-B. on a basis that gives primary emphasis to a special time survey of medical records personnel. If this appears to be impractical or inequitable, other bases may be used provided consideration is given to the use of these facilities by research personnel and others, including patients.

VII. DETERMINATION AND APPLICATION OF INDIRECT COST RATE OR RATES

A. *Indirect cost pools.* 1. Subject to (2) below, indirect costs allocated to organized research should be treated as a common pool, and the costs in such common pool should be distributed to individual research agreements benefiting therefrom on a single rate basis.

2. In some instances a single rate basis for use on all government research at a hospital may not be appropriate since it would not take into account those different environmental factors which may affect substantially the indirect costs applicable to a particular segment of government research at the institution. For this purpose, a particular segment of government research may be that performed under a single research agreement or it may consist of research under a group of research agreements performed in a common environment. The environmental factors are not limited to the physical location of the work. Other important factors are the level of the administrative support required, the nature of the facilities or other resources employed, the scientific disciplines or technical skills involved, the organizational arrangements used, or any combination thereof. Where a particular segment of government research is performed within an environment which appears to generate a significantly different level of indirect costs, provision should be made for a separate indirect cost pool applicable to such work. An example of this differential may be in the development of a separate indirect cost pool for a clinical research center grant. The separate indirect cost pool should be developed during the course of the regular distribution process, and the separate indirect cost rate resulting therefrom should be utilized provided it is determined that:

a. Such indirect cost rate differs significantly from that which would have obtained under (1) above; and

b. The volume of research work to which such rate would apply is material in relation to other government research at the institution.

3. It is a common practice for grants or contracts awarded to other institutions, typically University Schools of Medicine, to be performed on hospital premises. In these cases the hospital should develop a separate indirect cost pool applicable to the work under such grants or contracts. This pool should be developed by a selective distribution of only those indirect cost categories which benefit the work performed by the other institution, within the practical limits dictated by available data and the materiality of the amounts involved. Hospital costs determined to be allocable to grants or contracts awarded to another institution may not be recovered as a cost of grants or contracts awarded directly to the hospital.

B. *The distribution base.* Preferably, indirect costs allocated to organized research should be distributed to applicable research agreements on the basis of direct salaries and wages. However, where the use of salaries and wages results in an inequitable allocation of costs to the research agreements, total direct costs or a variation thereof, may be used in lieu of salaries and wages. Regardless of the base used, an indirect cost rate should be determined for each of the separate indirect cost pools developed pursuant to paragraph VII-A. The rate in each case should be stated as the percentage which the amount of the particular indirect cost pool is of the total direct salaries and wages (or other base selected) for all research agreements identified with such a pool.

C. *Negotiated lump sum for overhead.* A negotiated fixed amount in lieu of indirect costs may be appropriate for self-contained or off-campus research activities where the benefits derived from a hospital's indirect services cannot be readily determined. Such amount negotiated in lieu of indirect costs will be treated as an offset to the appropriate indirect cost pool after allocation to patient care, organized research, instruction and training, and other hospital activities. The base on which such remaining expenses are allocated should be appropriately adjusted.

D. *Predetermined overhead rates.* The utilization of predetermined fixed overhead rates may offer potential advantages in the administration of research agreements by facilitating the preparation of research budgets and permitting more expeditious close out of the agreements when the work is completed. Therefore, to the extent allowed by law, consideration may be given to the negotiation of predetermined fixed rates in those situations where the cost experience and other pertinent factors available are deemed sufficient to enable the Government and the hospital to reach a reasonable conclusion as to the probable level of the indirect cost rate for the ensuing accounting period.

VIII. SIMPLIFIED METHOD FOR SMALL INSTITUTIONS

A. *General.* 1. Where the total direct cost of all government-sponsored research and development work at a hospital in a year is minimal, the use of the abbreviated procedure described in paragraph VIII-B below may be acceptable in the determination of allowable indirect costs. This method may also be used to initially determine a provisional indirect cost rate for hospitals that have not previously established a rate. Under this abbreviated procedure, data taken directly from the institution's most recent annual financial report and immediately available supporting information will be utilized as a basis for determining the indirect cost rate applicable to research agreements at the institution.

2. The rigid formula approach provided under the abbreviated procedure has limitations which may preclude its use at some hospitals either because the minimum data required for this purpose are not readily available or because the application of the abbreviated procedure to the available data produces results which appear inequitable to the Government or the hospital. In any such case, indirect costs should be determined through use of the regular procedure rather than the abbreviated procedure.

3. In certain instances where the total direct cost of all government-sponsored research and development work at the hospital is more than minimal, the abbreviated procedure may be used if prior permission is obtained. This alternative will be granted only in those cases where it can be demonstrated that the step-down technique cannot be followed.

B. *Abbreviated procedure.* 1. Total expenditures as taken from the most recent annual financial report will be adjusted by eliminating from further consideration expenditures for capital items as defined in paragraph IX-B.4 and unallowable costs as defined under various headings in paragraph IX and paragraph III-E.

2. Total expenditures as adjusted under the foregoing will then be distributed among (a) expenditures applicable to administrative and general overhead functions, (b) expenditures applicable to all other overhead functions, and (c) expenditures for all other purposes. The first group shall include amounts associated with the functional categories, Administration and General, and Dietary, as defined in paragraph VI. The second group shall include Depreciation, Operation of Plant, Maintenance of Plant, and Housekeeping. The third group—expenditures for all other purposes—shall include the amounts applicable to all other activities, namely, patient care, organized research, instruction and training, and other hospital activities as defined under paragraph II-E. For the purposes of this section, the functional categories of Laundry and Linen, Maintenance of Personnel, and Medical Records and Library as defined in paragraph VI shall be considered as expenditures for all other purposes.

3. The expenditures distributed to the first two groups in paragraph VIII-B.2 should then be adjusted by those receipts or negative expenditure types of transactions which tend to reduce expense items allocable to research agreements as indirect costs. Examples of such receipts or negative expenditures are itemized in paragraph III-E.1.

4. In applying the procedures in paragraphs VIII-B.1 and B.2, the cost of unallowable activities such as Gift Shop, Investment Property Management, Fund Raising, and Public Relations, when they benefit from the hospital's indirect cost services, should be treated as expenditures for all other purposes. Such activities are presumed to benefit from the hospital's indirect cost services when they include salaries of personnel working in the hospital. When they do not include such salaries, they should be eliminated from the indirect cost rate computation.

5. The indirect cost rate will then be computed in two stages. The first stage requires the computation of an Administrative and General rate component. This is done by applying a ratio of research direct costs over total direct costs to the Administrative and General pool developed under paragraphs VIII-B.2 and B.3 above. The resultant amount—that which is allocable to research—is divided by the direct research cost base. The second stage requires the computation of an All other Indirect Cost rate component. This is done by applying a ratio of research direct space over total direct space to All Other Indirect Cost pool developed under paragraphs VIII-B.2 and B.3 above. The resultant amount—that which is allocable to research—is divided by the direct research cost base.

The total of the two rate components will be the institution's indirect cost rate. For the purposes of this section, the research direct cost or space and total direct cost or space will be that cost or space identified with the functional categories classified under Expenditures for all other purposes under paragraph VIII-B.2.

IX. GENERAL STANDARDS FOR SELECTED ITEMS OF COST

A. *General*. This section provides standards to be applied in establishing the allowability of certain items involved in determining cost. These standards should apply irrespective of whether a particular item of cost is properly treated as direct cost or indirect cost. Failure to mention a particular item of cost in the standards is not intended to imply that it is either allowable or unallowable; rather, determination as to allowability in each case should be based on the treatment or standards provided for similar or related items of cost. In case of discrepancy between the provisions of a specific research agreement and the applicable standards provided, the provisions of the research agreement should govern. However, in some cases advance understandings should be reached on particular cost items in order that the full costs of research be supported. The extent of allowability of the selected items of cost covered in this section has been stated to apply broadly to many accounting systems in varying environmental situations. Thus, as to any given research agreement, the reasonableness and allocability of certain items of costs may be difficult to determine, particularly in connection with hospitals which have medical school or other affiliations. In order to avoid possible subsequent disallowance or dispute based on unreasonableness or nonallocability, it is important that prospective recipients of federal funds particularly those whose work is predominantly or substantially with the Government, seek agreement with the Government in advance of the incurrence of special or unusual costs in categories where reasonableness or allocability are difficult to determine. Such agreement may also be initiated by the Government. Any such agreement should be incorporated in the research agreement itself. However, the absence of such an advance agreement on any element of cost will not in itself serve to make that element either allowable or unallowable. Examples of costs on which advance agreements may be particularly important are:

1. Facilities costs, such as;

a. Depreciation

b. Rental

c. Use charges for fully depreciated assets

d. Idle facilities and idle capacity

e. Plant reconversion

f. Extraordinary or deferred maintenance and repair

g. Acquisition of automatic data processing equipment.

2. Preaward costs

3. Non-hospital professional activities

4. Self-insurance

5. Support services charged directly (computer services, printing and duplicating services, etc.)

6. Employee compensation, travel, and other personnel costs, including;

a. Compensation for personal service, including wages and salaries, bonuses and incentives, premium payments, pay for time not worked, and supplementary compensation and benefits, such as pension and retirement, group insurance, severance pay plans, and other forms of compensation

b. Morale, health, welfare, and food service and dormitory costs

c. Training and education costs

d. Relocation costs, including special or mass personnel movement

B. *Selected items*—1. *Advertising costs*. The term advertising costs means the costs of advertising media and corollary administrative costs. Advertising media include magazines, newspapers, radio and television programs, direct mail, exhibits, and the like. The only advertising costs allowable are those which are solely for;

a. The recruitment of persons required for the performance by the institution of obligations arising under the research agreement, when considered in conjunction with all other recruitment costs as set forth in paragraph IX-B.34.

b. The procurement of scarce items for the performance of the research agreement; or

c. The disposal of scrap or surplus materials acquired in the performance of the research agreement.

Costs of this nature, if incurred for more than one research agreement or for both research agreement work and other work of the institution, are allowable to the extent that the principles in paragraphs IV and V are observed.

2. *Bad debts*. Losses arising from uncollectible accounts and other claims and related collection and legal costs are unallowable except that a bad debt may be included as a direct cost of the research agreement to the extent that it is caused by a research patient and approved by the awarding agency. This inclusion is only intended to cover the situation of the patient admitted for research purposes who subsequently or in conjunction with the research receives clinical care for which a charge is made to the patient. If, after exhausting all means of collecting these charges, a bad debt results, it

may be considered an appropriate charge to the research agreement.

3. *Bonding costs.* a. Bonding costs arise when the Government requires assurance against financial loss to itself or others by reason of the act or default of the hospital. They arise also in instances where the hospital requires similar assurance.

Included are such types as bid, performance, payment, advance payment, infringement, and fidelity bonds.

b. Costs of bonding required pursuant to the terms of the research agreement are allowable.

c. Costs of bonding required by the hospital in the general conduct of its business are allowable to the extent that such bonding is in accordance with sound business practice and the rates and premiums are reasonable under the circumstances.

4. *Capital expenditures.* The costs of equipment, buildings, and repairs which materially increase the value or useful life of buildings or equipment should be capitalized and are unallowable except as provided for in the research agreement.

5. *Civil defense costs.* Civil defense costs are those incurred in planning for, and the protection of life and property against the possible effects of enemy attack. Reasonable costs of civil defense measures (including costs in excess of normal plant protection costs, first-aid training and supplies, fire-fighting training, posting of additional exit notices and directions, and other approved civil defense measures) undertaken on the institution's premises pursuant to suggestions or requirements of civil defense authorities are allowable when distributed to all activities of the institution. Capital expenditures for civil defense purposes will not be allowed, but a use allowance or depreciation may be permitted in accordance with provisions set forth elsewhere. Costs of local civil defense projects not on the institution's premises are unallowable.

6. *Communication costs.* Costs incurred for telephone services, local and long distance telephone calls, telegrams, radiograms, postage, and the like are allowable.

7. *Compensation for personal services*—a. *General.* Compensation for personal services covers all remuneration paid currently or accrued to employees of the hospital for services rendered during the period of performance under government research agreements. Such remuneration includes salaries, wages, staff benefits (see paragraph IX-B.10), and pension plan costs (see paragraph IX-B.25). The costs of such remuneration are allowable to the extent that the total compensation to individual employees is reasonable for the services rendered and conforms to the established policy of the institution consistently applied, and provided that the charges for work performed directly on government research agreements and for other work allocable as indirect costs to sponsored research are determined and supported as hereinafter provided. For nonprofit, non-proprietary institutions, where federally supported programs constitute less than a preponderance of the activity at the institution the primary test of reasonableness will be to require that the institution's compensation policies be applied consistently both to federally-sponsored and nonsponsored activities alike. However, where special circumstances so dictate a contractual clause may be utilized which calls for application of the test of comparability in determining the reasonableness of compensation.

b. *Payroll distribution.* Amounts charged to organized research for personal services, regardless of whether treated as direct costs or allocated as indirect costs, will be based on hospital payrolls which have been approved and documented in accordance with generally accepted hospital practices. In order to develop necessary direct and indirect allocations of cost, supplementary data on time or effort as provided in paragraph (c) below, normally need be required only for individuals whose compensation is properly chargeable to two or more research agreements or to two or more of the following broad functional categories: (1) Patient care; (2) organized research; (3) instruction and training; (4) indirect activities as defined in paragraph V-A; or (5) other hospital activities as defined in paragraph II-E.

c. *Reporting time or effort.* Charges for salaries and wages of individuals other than members of the professional staff will be supported by daily time and attendance and payroll distribution records. For members of the professional staff, current and reasonable estimates of the percentage distribution of their total effort may be used as support in the absence of actual time records. The term professional staff for purposes of this section includes physicians, research associates, and other personnel performing work at responsible levels of activities. These personnel normally fulfill duties, the competent performance of which usually requires persons possessing degrees from accredited institutions of higher learning and/or state licensure. In order to qualify as current and reasonable, estimates must be made no later than one month (though not necessarily a calendar month) after the month in which the services were performed.

d. *Preparation of estimates of effort.* Where required under paragraph (c) above, estimates of effort spent by a member of the professional staff on each research agreement should be prepared by the individual who performed the services or by a responsible individual such as a department head or supervisor having first-hand knowledge of the services performed on each research agreement. Estimates must show the allocation of effort between organized research and all other hospital activities in terms of the percentage of total effort devoted to each of the broad functional categories referred to in (b) above. The estimate of effort spent on a research agreement may include a reasonable amount of time spent in activities contributing and intimately related to work under the agreement, such as preparing and delivering special lectures about specific aspects of the ongoing research, writing research reports and articles, participating in appropriate research seminars, consulting with colleagues with respect to related research, and attending appropriate scientific meetings and conferences. The term "all other hospital activities" would include departmental research, administration, committee work, and public services undertaken on behalf of the hospital.

e. *Application of budget estimates.* Estimates determined before the performance of services, such as budget estimates on a monthly, quarterly, or yearly basis do not qualify as estimates of effort spent.

f. *Non-hospital professional activities.* A hospital must not alter or waive hospital-wide policies and practices dealing with the permissible extent of professional services over and above those traditionally performed without extra hospital compensation, unless such arrangements are specifically authorized by the sponsoring agency. Where hospital-wide policies do not adequately define the permissible extent of consultantships or other non-hospital activities undertaken for extra pay, the Government may require that the effort of professional staff working under research agreements be allocated as between (1) hospital activities, and (2) non-hospital professional activities. If the sponsoring agency should consider the extent of non-hospital professional effort excessive, appropriate arrangements governing compensation will be negotiated on a case by case basis.

g. *Salary rates for part-time appointments.* Charges for work performed on government research by staff members having only part-time appointments will be determined at a rate not in excess of that for which he is regularly paid for his part-time staff assignment.

8. *Contingency provisions.* Contributions to a contingency reserve or any similar provisions made for events the occurrence of which cannot be foretold with certainty as to time, intensity, or with an assurance of their happening, are unallowable.

9. *Depreciation and use allowances.* a. Hospitals may be compensated for the use of buildings, capital improvements and usable equipment on hand through depreciation or use allowances. Depreciation is a charge to current operations which distributes the cost of a tangible capital asset, less estimated residual value, over the estimated useful life of the asset in a systematic and logical manner. It does not involve a process of valuation. Useful life has reference to the prospective period of economic usefulness in the particular hospital's operations as distinguished from physical life. Use allowances are the means of allowing compensation when depreciation or other equivalent costs are not considered.

b. Due consideration will be given to government-furnished research facilities utilized by the institution when computing use allowances and/or depreciation if the government-furnished research facilities are material in amount. Computation of the use allowance and/or depreciation will exclude both the cost or any portion of the cost of grounds, buildings and equipment borne by or donated by the Federal Government, irrespective of where title was originally vested or where it presently resides, and secondly, the cost of grounds. Capital expenditures for land improvements (paved areas, fences, streets, sidewalks, utility conduits, and similar improvements not already included in the cost of buildings) are allowable provided the systematic amortization of such capital expenditures has been provided in the institution's books of accounts, based on reasonable determinations of the probable useful lives of the individual items involved, and the share allocated to organized research is developed from the amount thus amortized for the base period involved.

c. Normal depreciation on a hospital's plant, equipment, and other capital facilities, except as excluded by (d) below, is an allowable element of research cost provided that the amount thereof is computed:

1. Upon the property cost basis used by the hospital for Federal Income Tax purposes (See section 167 of the Internal Revenue Code of 1954); or

2. In the case of non-profit or tax exempt organizations, upon a property cost basis which could have been used by the hospital for Federal Income Tax purposes, had such hospital been subject to the payment of income tax; and in either case

3. By the consistent application to the assets concerned of any generally accepted accounting method, and subject to the limitations of the Internal Revenue Code of 1954 as amended, including—

i. The straight line method;

ii. The declining balance method, using a rate not exceeding twice the rate which would have been used had the annual allowance been computed under the method described in (i) above;

iii. The sum of the years-digits method; and

iv. Any other consistent method productive of an annual allowance which, when added to all allowances for the period commencing with the use of the property and including the current year, does not during the first two-thirds of the useful life of the property exceed the total of such allowances which would have been used had such allowances been computed under the method described in (ii) above.

d. Where the depreciation method is followed, adequate property records must be maintained. The period of useful service (service life) established in each case for usable capital assets must be determined on a realistic basis which takes into consideration such factors as type of construction, nature of the equipment used, technological developments in the particular research area, and the renewal and replacement policies followed for the individual items or classes of assets involved. Where the depreciation method is introduced for application to assets acquired in prior years, the annual charges therefrom must not exceed the amounts that would have resulted had the depreciation method been in effect from the date of acquisition of such assets.

e. Depreciation on idle or excess facilities shall not be allowed except on such facilities as are reasonably necessary for standby purposes.

f. Where an institution elects to go on a depreciation basis for a particular class of assets, no depreciation, rental or use charge may be allowed on any such assets that would be viewed as fully depreciated; provided, however, that reasonable use charges may be negotiated for any such assets if warranted after taking into consideration the cost of the facility or item involved, the estimated useful life remaining at time of negotiation, the actual replacement policy followed in the light of service lives used for calculating depreciation, the effect of any increased maintenance charges or decreased efficiency due to age, and any other factors pertinent to the utilization of the facility or item for the purpose contemplated.

g. Hospitals which choose a depreciation allowance for assets purchased prior to 1966 based on a percentage of operating costs in lieu of normal depreciation for purposes of reimbursement under Pub. L. 89-97 (Medicare) shall utilize that method for determining depreciation applicable to organized research.

The operating costs to be used are the lower of the hospital's 1965 operating costs or the hospital's current year's allowable costs. The percent to be applied is 5 percent starting with the year 1966-67, with such percentage being uniformity reduced by one-half percent each succeeding year. The allowance based on operating costs is in addition to regular depreciation on assets acquired after 1965. However, the combined amount of such allowance on pre-1966 assets and the allowance for actual depreciation on assets acquired after 1965 may not exceed 6 percent of the hospital's allowable cost for the current year. After total depreciation has been computed, allocation methods are used to determine the share attributable to organized research.

For purposes of this section, "Operating Costs" means the total costs incurred by the hospital in operating the institution, and includes patient care, research, and other activities. "Allowable Costs" means operating costs less unallowable costs as defined in these principles; by the application of allocation methods to the total amount of such allowable costs, the share attributable to Federally-sponsored research is determined.

A hospital which elects to use this procedure under Pub. L. 89-97 and subsequently changes to an actual depreciation basis on pre-1966 assets in accordance with the option afforded under the Medicare program shall simultaneously change to an actual depreciation basis for organized research.

Where the hospital desires to change to actual depreciation but either has no historical cost records or has incomplete records, the determination of historical cost could be made through appropriate means involving expert consultation with the determination being subject to review and approval by the Department of Health and Human Services.

h. Where the use allowance method is followed, the use allowance for buildings and improvements will be computed at an annual rate not exceeding two percent of acquisition cost. The use allowance for equipment will be computed at an annual rate not exceeding six and two-thirds percent of acquisition cost of usable equipment in those cases where the institution maintains current records with respect to such equipment on hand. Where the institution's records reflect only the cost (actual or estimated) of the original complement of equipment, the use allowance will be computed at an annual rate not exceeding ten percent of such cost. Original complement for this purpose means the complement of equipment initially placed in buildings to perform the functions currently being performed in such buildings; however, where a permanent change in the function of a building takes place, a redetermination of the original complement of equipment may be made at that time to establish a new original complement. In those cases where no equipment records are maintained, the institution will justify a reasonable estimate of the acquisition cost of usable equipment which may be used to compute the use allowance at an annual rate not exceeding six and two-thirds percent of such estimate.

i. Depreciation and/or use charges should usually be allocated to research and other activities as an indirect cost.

10. *Employee morale, health, and welfare costs and credits.* The costs of house publications, health or first-aid benefits, recreational activities, employees' counseling services, and other expenses incurred in accordance wtih the hospital's established practice or custom for the improvement of working conditions, employer-employee relations, employee morale, and employee performance, are allowable. Such costs will be equitably apportioned to all activities of the hospital. Income generated from any of these activities will be credited to the cost thereof unless such income has been irrevocably set over to employee welfare organizations.

11. *Entertainment costs.* Except as pertains to 10 above, costs incurred for amusement, social activities, entertainment, and any items relating thereto, such as meals, lodging, rentals, transportation, and gratuities are unallowable.

12. *Equipment and other facilities.* The cost of equipment or other facilities are allowable on a direct charge basis where such purchases are approved by the sponsoring agency concerned or provided for by the terms of the research agreement.

13. *Fines and penalties.* Costs resulting from violations of, or failure of the institution to comply with federal, state and local laws and regulations are unallowable except when incurred as a result of compliance with specific provisions of the research agreement, or instructions in writing from the awarding agency.

14. *Insurance and indemnification.* a. Costs of insurance required or approved and maintained pursuant to the research agreement are allowable.

b. Costs of other insurance maintained by the hospital in connection with the general conduct of its activities are allowable subject to the following limitations: (1) Types and extent and cost of coverage must be in accordance with sound institutional practice; (2) costs of insurance or of any contributions to any reserve covering the risk of loss of or damage to government owned property are unallowable except to the extent that the Government has specifically required or approved such costs; and (3) costs of insurance on the lives of officers or trustees are unallowable except where such insurance is part of an employee plan which is not unduly restricted.

c. Contributions to a reserve for an approved self-insurance program are allowable to the extent that the types of coverage, extent of coverage, and the rates and premiums would have been allowed had insurance been purchased to cover the risks. Such contributions are subject to prior approval of the Government.

d. Actual losses which could have been covered by permissible insurance (through an approved self-insurance program or otherwise) are unallowable unless expressly provided for in the research agreement, except that costs incurred because of losses not covered under nominal deductible insurance coverage provided in keeping with sound management practice as well as minor losses not covered by insurance such as spoilage, breakage and disappearance of small hand tools which occur in the ordinary course of operations are allowable.

15. *Interest, fund raising and investment management costs.* a. Costs incurred for interest on borrowed capital or temporary use of endowment funds, however represented, are unallowable.

b. Costs of organized fund raising, including financial campaigns, endowment drives, solicitation of gifts and bequests, and similar expenses incurred solely to raise capital or obtain contributions are not allowable.

c. Costs of investment counsel and staff and similar expenses incurred solely to enhance income from investments are not allowable.

d. Costs related to the physical custody and control of monies and securities are allowable.

16. *Labor relations costs.* Costs incurred in maintaining satisfactory relations between the hospital and its employees, including costs of labor management committees, employees' publications, and other related activities are allowable.

17. *Losses on research agreements or contracts.* Any excess of costs over income under any agreement or contract of any nature is unallowable. This includes, but is not limited to, the hospital's contributed portion by reason of cost-sharing agreements, under-recoveries through negotiation of flat amounts for overhead, or legal or administrative limitations.

18. *Maintenance and repair costs.* a. Costs necessary for the upkeep of property (including government property unless otherwise provided for), which neither add to the permanent value of the property nor appreciably prolong its intended life, but keep it in an efficient operating condition, are to be treated as follows:

1. Normal maintenance and repair costs are allowable;

2. Extraordinary maintenance and repair costs are allowable, provided they are allocated to the periods to which applicable for purposes of determining research costs.

b. Expenditures for plant and equipment, including rehabilitation thereof, which according to generally accepted accounting principles as applied under the hospital's established policy, should be capitalized and subjected to depreciation, are allowable only on a depreciation basis.

19. *Material costs.* Costs incurred for purchased materials, supplies and fabricated parts directly or indirectly related to the research agreement, are allowable. Purchases made specifically for the research agreement should be charged thereto at their actual prices after deducting all cash discounts, trade discounts, rebates, and allowances received by the institution. Withdrawals from general stores or stockrooms should be charged at their cost under any recognized method of pricing stores withdrawals conforming to sound accounting practices consistently followed by the hospital. Incoming transportation charges are a proper part of material cost. Direct material cost should include only the materials and supplies actually used for the performance of the research agreement, and due credit should be given for any excess materials retained or returned to vendors. Due credit should be given for all proceeds or value received for any scrap resulting from work under the research agreement. Where government donated or furnished material is used in performing the research agreement, such material will be used without charge.

20. *Memberships, subscriptions and professional activity costs.* a. Costs of the hospital's membership in civic, business, technical and professional organizations are allowable.

b. Costs of the hospital's subscriptions to civic, business, professional and technical periodicals are allowable.

c. Costs of meetings and conferences, when the primary purpose is the dissemination of technical information, are allowable. This includes costs of meals, transportation, rental of facilities, and other items incidental to such meetings or conferences.

21. *Organization costs.* Expenditures such as incorporation fees, attorneys' fees, accountants' fees, brokers' fees, fees to promoters and organizers in connection with (a) organization or reorganization of a hospital, or (b) raising capital, are unallowable.

22. *Other business expenses.* Included in this item are such recurring expenses as registry and transfer charges resulting from changes in ownership of securities issued by the hospital, cost of shareholders meetings preparation and publication of reports to shareholders, preparation and submission of required reports and forms to taxing and other regulatory bodies, and incidental costs of directors and committee meetings. The above and similar costs are allowable when allocated on an equitable basis.

23. *Patient care.* The cost of routine and ancillary or special services to research patients is an allowable direct cost of research agreements.

a. Routine services shall include the costs of the regular room, dietary and nursing services, minor medical and surgical supplies and the use of equipment and facilities for which a separate charge is not customarily made.

b. Ancillary or special services are the services for which charges are customarily made in addition to routine services, such as operating rooms, anesthesia, laboratory, BMR-EKG, etc.

c. Patient care, whether expressed as a rate or an amount, shall be computed in a manner consistent with the procedures used to determine reimbursable costs under Pub. L. 89-97 (Medicare Program) as defined under the "Principles Of Reimbursement For Provider Costs" published by the Social Security Administration of the Department of Health and Human Services. The allowability of specific categories of cost shall be in accordance with those principles rather than the principles for research contained herein. In the absence of participation in the Medicare program by a hospital, all references to the Medicare program in these principles shall be construed as meaning the Medicaid program.

i. Once costs have been recognized as allowable, the indirect costs or general service center's cost shall be allocated (stepped-down) to special service centers, and all patient and nonpatient costs centers based upon actual services received or benefiting these centers.

ii. After allocation, routine and ancillary costs shall be apportioned to scatter-bed research patients on the same basis as is used to apportion costs to Medicare patients, i.e. using either the departmental method or the combination method, as those methods are defined by the Social Security Administration; except that final settlement shall be on a grant-by-grant basis. However, to the extent that the Social Security Administration has recognized any other method of cost apportionment, that method generally shall also be recognized as applicable to the determination of research patient care costs.

iii. A cost center must be established on Medicare reimbursement forms for each discrete-bed unit grant award received by a hospital. Routine costs should be stepped-down to this line item(s) in the normal course of stepping-down costs under Medicare/Medicaid requirements. However, in stepping-down routine costs, consideration must be given to preventing a step-down of those costs to discrete-bed unit line items that have already been paid for directly by the grant, such as bedside nursing costs. Ancillary costs allocable to research discrete-bed units shall be determined and proposed in accordance with Section 23.c.ii.

d. Where federally sponsored research programs provide specifically for the direct reimbursement of nursing, dietary, and other services, appropriate adjustment must

e made to patient care costs to preclude
uplication and/or misallocation of costs.

24. *Patent costs.* Costs of preparing disclo-
ures, reports and other documents required
y the research agreement and of searching
e art to the extent necessary to make
ch invention disclosures are allowable. In
ccordance with the clauses of the research
greement relating to patents, costs of pre-
aring documents and any other patent
sts, in connection with the filing of a
atent application where title is conveyed to
e Government, are allowable. (See also
aragraph IX-B.36.)

25. *Pension plan costs.* Costs of the hospi-
l's pension plan which are incurred in ac-
rdance with the established policies of the
stitution are allowable, provided such poli-
es meet the test of reasonableness and the
ethods of cost allocation are not discrimi-
atory, and provided appropriate adjust-
ents are made for credits or gains arising
t of normal and abnormal employee turn-
er or any other contingencies that can
sult in forfeitures by employees which
ure to the benefit of the hospital.

26. *Plan security costs.* Necessary ex-
nses incurred to comply with government
curity requirements including wages, uni-
rms and equipment of personnel engaged
plant protection are allowable.

27. *Preresearch agreement costs.* Costs in-
rred prior to the effective date of the re-
arch agreement, whether or not they
uld have been allowable thereunder if in-
rred after such date, are unallowable
less specifically set forth and identified in
e research agreement.

28. *Professional services costs.* a. Costs of
ofessional services rendered by the mem-
rs of a particular profession who are not
ployees of the hospital are allowable sub-
t to (b) and (c) below when reasonable in
ation to the services rendered and when
t contingent upon recovery of the costs
m the Government. Retainer fees to be
owable must be reasonably supported by
idence of services rendered.

. Factors to be considered in determining
e allowability of costs in a particular case
lude (1) the past pattern of such costs,
rticularly in the years prior to the award
government research agreements on the
titution's total activity; (2) the nature
d scope of managerial services expected
the institution's own organizations; and
whether the proportion of government
rk to the hospital's total activity is such
to influence the institution in favor of in-
rring the cost, particularly where the
vices rendered are not of a continuing
ture and have little relationship to work
der government research agreements.

. Costs of legal, accounting and consult-
services, and related costs incurred in
nection with organization and reorgani-
ion or the prosecution of claims against the Government are unallowable. Costs of legal, accounting and consulting services, and related costs incurred in connection with patent infringement litigation are unallowable unless otherwise provided for in the research agreement.

29. *Profits and losses on disposition of plant equipment, or other assets.* Profits or losses of any nature arising from the sale or exchange of plant, equipment, or other capital assets, including sales or exchange of either short- or long-term investments, shall be excluded in computing research agreement costs.

30. *Proposal costs.* Proposal costs are the costs of preparing bids or proposals on potential government and non-government research agreements or projects, including the development of technical data and cost data necessary to support the institution's bids or proposals. Proposal costs of the current accounting period of both successful and unsuccessful bids and proposals normally should be treated as indirect costs and allocated currently to all activities of the institution, and no proposal costs of past accounting periods will be allocable in the current period to the government research agreement. However, the institution's established practices may be to treat proposal costs by some other recognized method. Regardless of the methods used, the results obtained may be accepted only if found to be reasonable and equitable.

31. *Public information services costs.* Costs of news releases pertaining to specific research or scientific accomplishment are unallowable unless specifically authorized by the sponsoring agency.

32. *Rearrangement and alteration costs.* Costs incurred for ordinary or normal rearrangement and alteration of facilities are allowable. Special rearrangement and alteration costs incurred specifically for a project are allowable only as a direct charge when such work has been approved in advance by the sponsoring agency concerned.

33. *Reconversion costs.* Costs incurred in the restoration or rehabilitation of the institution's facilities to approximately the same condition existing immediately prior to commencement of government research agreement work, fair wear and tear excepted, are allowable.

34. *Recruiting costs.* a. Subject to (b), (c), and (d) below, and provided that the size of the staff recruited and maintained is in keeping with workload requirements, costs of "help wanted" advertising, operating costs of an employment office necessary to secure and maintain an adequate staff, costs of operating an aptitude and educational testing program, travel costs of employees while engaged in recruiting personnel, travel costs of applicants for interviews for prospective employment, and relocation

costs incurred incident to recruitment of new employees are allowable to the extent that such costs are incurred pursuant to a well managed recruitment program. Where an institution uses employment agencies, costs not in excess of standard commercial rates for such services are allowable.

b. In publications, costs of help wanted advertising that includes color, includes advertising material for other than recruitment purposes, or is excessive in size (taking into consideration recruitment purposes for which intended and normal institutional practices in this respect) are unallowable.

c. Costs of help wanted advertising, special emoluments; fringe benefits, and salary allowances incurred to attract professional personnel from other institutions that do not meet the test of reasonableness or do not conform with the established practices of the institution are unallowable.

d. Where relocation costs incurred incident to recruitment of a new employee have been allowed either as an allocable direct or indirect cost, and the newly hired employee resigns for reasons within his control within twelve months after hire, the institution will be required to refund or credit such relocations costs as were charged to the Government.

35. *Rental costs (including sale and leaseback of facilities).* a. Rental costs of land, building, and equipment and other personal property are allowable if the rates are reasonable in light of such factors as rental costs of comparable facilities and market conditions in the area, the type, life expectancy, condition, and value of the facilities leased, options available, and other provisions of the rental agreement. Application of these factors, in situations where rentals are extensively used, may involve among other considerations comparison of rental costs with the amount which the hospital would have received had it owned the facilities.

b. Charges in the nature of rent between organizations having a legal or other affiliation or arrangement such as hospitals, medical schools, foundations, etc., are allowable to the extent such charges do not exceed the normal costs of ownership such as depreciation, taxes, insurance, and maintenance, provided that no part of such costs shall duplicate any other allowed costs.

c. Unless otherwise specifically provided in the agreement, rental costs specified in sale and lease-back agreements incurred by hospitals through selling plant facilities to investment organizations such as insurance companies or to private investors, and concurrently leasing back the same facilities are allowable only to the extent that such rentals do not exceed the amount which the hospital would have received had it retained legal title to the facilities.

36. *Royalties and other costs for use of patents.* Royalties on a patent or amortization of the cost of acquiring a patent or invention or rights thereto necessary for the proper performance of the research agreement and applicable to tasks or processes thereunder are allowable unless the Government has a license or the right to free use of the patent, the patent has been adjudicated to be invalid, or has been administratively determined to be invalid, the patent is considered to be unenforceable, or the patent has expired.

37. *Severance pay.* a. Severance pay is compensation in addition to regular salaries and wages which is paid by a hospital to employees whose services are being terminated. Costs of severance pay are allowable only to the extent that such payments are required by law, by employer-employee agreement, by established policy that constitutes in effect an implied agreement on the institution's part, or by circumstances of the particular employment.

b. Severance payments that are due to normal, recurring turnover, and which otherwise meet the conditions of (a) above may be allowed provided the actual costs of such severance payments are regarded as expenses applicable to the current fiscal year and are equitably distributed among the institution's activities during that period.

c. Severance payments that are due to abnormal or mass terminations are of such conjectural nature that allowability must be determined on a case-by-case basis. However, the Government recognizes its obligation to participate to the extent of its fair share in any specific payment.

38. *Specialized service facilities operated by a hospital.* a. The costs of institutional services involving the use of highly complex and specialized facilities such as electronic computers and reactors are allowable provided the charges therefor meet the conditions of (b) or (c) below, and otherwise take into account any items of income or federal financing that qualify as applicable credits under paragraph III-E.

b. The costs of such hospital services normally will be charged directly to applicable research agreements based on actual usage or occupancy of the facilities at rates that (1) are designed to recover only actual costs of providing such services, and (2) are applied on a nondiscriminatory basis as between organized research and other work of the hospital including commercial or accommodation sales and usage by the hospital for internal purposes. This would include use of such facilities as radiology, laboratories, maintenance men used for a special purpose, medical art, photography, etc.

c. In the absence of an acceptable arrangement for direct costing as provided in (b) above, the costs incurred for such institu-

onal services may be assigned to research
greements as indirect costs, provided the
ethods used achieve substantially the
me results. Such arrangements should be
orked out in coordination with all govern-
ent users of the facilities in order to
sure equitable distribution of the indirect
sts.
39. *Special administrative costs.* Costs in-
rred for general public relations activities,
talogs, alumni activities, and similar serv-
es are unallowable.
40. *Staff and/or employee benefits.* a. Staff
nd/or employee benefits in the form of
gular compensation paid to employees
ring periods of authorized absences from
e job such as for annual leave, sick leave,
ilitary leave and the like are allowable
ovided such costs are absorbed by all hos-
tal activities including organized research
proportion to the relative amount of time
effort actually devoted to each.
b. Staff benefits in the form of employer
ntributions or expenses for Social Securi-
taxes, employee insurance, Workmen's
mpensation insurance, the Pension Plan
e paragraph IX-B.25), hospital costs or
mission of hospital charges to the extent
costs for individual employees or their
milies, and the like are allowable provided
ch benefits are granted in accordance
th established hospital policies, and pro-
led such contributions and other expenses
ether treated as indirect costs or an in-
ement of direct labor costs are distributed
particular research agreements and other
tivities in a manner consistent with the
ttern of benefits accruing to the individ-
ls or groups of employees whose salaries
d wages are chargeable to such research
reements and other activities.
1. *Taxes.* a. In general, taxes which the
spital is required to pay and which are
id or accrued in accordance with general-
accepted accounting principles, and pay-
nts made to local governments in lieu of
es which are commensurate with the
al government services received are al-
able except for (1) taxes from which ex-
ptions are available to the hospital di-
tly or which are available to the hospital
ed on an exemption afforded the Gov-
ment and in the latter case when the
nsoring agency makes available the nec-
ary exemption certificates, (2) special as-
ments on land which represent capital
provements, and (3) Federal Income
es.
Any refund of taxes, interest, or penal-
, and any payment to the hospital of in-
st thereon attributable to taxes, interest
penalties, which were allowed as research
eement costs will be credited or paid to
Government in the manner directed by
Government provided any interest actu-
paid or credited to a hospital incident
refund of tax, interest, and penalty will

be paid or credited to the Government only to the extent that such interest accrued over the period during which the hospital had been reimbursed by the Government for the taxes, interest, and penalties.

42. *Transportation costs.* Costs incurred for inbound freight, express, cartage, postage and other transportation services relating either to goods purchased, in process, or delivered are allowable. When such costs can readily be identified with the items involved, they may be charged directly as transportation costs or added to the cost of such items. Where identification with the material received cannot readily be made, inbound transportation costs may be charged to the appropriate indirect cost accounts if the institution follows a consistent equitable procedure in this respect. Outbound freight, if reimbursable under the terms of the research agreement, should be treated as a direct cost.

43. *Travel costs.* a. Travel costs are the expenses for transportation, lodging, subsistence, and related items incurred by employees who are in travel status on official business of the hospital. Such costs may be charged on an actual basis, on a per diem or mileage basis in lieu of actual costs incurred, or on a combination of the two provided the method used is applied to an entire trip and not to selected days of the trip, and results in charges consistent with those normally allowed by the institution in its regular operations.

b. Travel costs are allowable subject to (c) and (d) below when they are directly attributable to specific work under a research agreement or when they are incurred in the normal course of administration of the hospital or a department or research program thereof.

c. The difference in cost between first class air accommodations and less than first class air accommodations is unallowable except when less than first class air accommodations are not reasonably available to meet necessary mission requirements such as where less than first class accommodations would (1) require circuitous routing, (2) require travel during unreasonable hours, (3) greatly increase the duration of the flight, (4) result in additional costs which would offset the transportation savings, or (5) offer accommodations which are not reasonably adequate for the medical needs of the traveler.

d. Costs of personnel movements of a special or mass nature are allowable only when authorized or approved in writing by the sponsoring agency or its authorized representative.

44. *Termination costs applicable to contracts.* a. Contract terminations generally give rise to the incurrence of costs or to the need for special treatment of costs which

would not have arisen had the contract not been terminated. Items peculiar to termination are set forth below. They are to be used in conjunction with all other provisions of these principles in the case of contract termination.

b. The cost of common items of material reasonably usable on the hospital's other work will not be allowable unless the hospital submits evidence that it could not retain such items at cost without sustaining a loss. In deciding whether such items are reasonably usable on other work of the institution, consideration should be given to the hospital's plans for current scheduled work or activities including other research agreements. Contemporaneous purchases of common items by the hospital will be regarded as evidence that such items are reasonably usable on the hospital's other work. Any acceptance of common items as allowable to the terminated portion of the contract should be limited to the extent that the quantities of such items on hand, in transit, and on order are in excess of the reasonable quantitative requirement of other work.

c. If in a particular case, despite all reasonable efforts by the hospital, certain costs cannot be discontinued immediately after the effective date of termination, such costs are generally allowable within the limitations set forth in these principles, except that any such costs continuing after termination due to the negligent or willful failure of the hospital to discontinue such costs will be considered unacceptable.

d. Loss of useful value of special tooling and special machinery and equipment is generally allowable, provided (1) such special tooling, machinery or equipment is not reasonably capable of use in the other work of the hospital; (2) the interest of the Government is protected by transfer of title or by other means deemed appropriate by the contracting officer; and (3) the loss of useful value as to any one terminated contract is limited to that portion of the acquisition cost which bears the same ratio to the total acquisition cost as the terminated portion of the contract bears to the entire terminated contract and other government contracts for which the special tooling, special machinery or equipment was acquired.

e. Rental costs under unexpired leases are generally allowable where clearly shown to have been reasonably necessary for the performance of the terminated contract, less the residual value of such leases, if (1) the amount of such rental claimed does not exceed the reasonable use value of the property leased for the period of the contract and such further period as may be reasonable; and (2) the hospital makes all reasonable efforts to terminate, assign, settle, or otherwise reduce the cost of such lease. There also may be included the cost of alterations of such leased property, provided such alterations were necessary for the performance of the contract and of reasonable restoration required by the provisions of the lease.

f. Settlement expenses including the following are generally allowable: (1) Accounting, legal, clerical, and similar costs reasonably necessary for the preparation and presentation to contracting officers of settlement claims and supporting data with respect to the terminated portion of the contract and the termination and settlement of subcontracts; and (2) reasonable costs for the storage, transportation, protection, and disposition of property provided by the Government or acquired or produced by the institution for the contract.

g. Subcontractor claims including the allocable portion of claims which are common to the contract and to other work of the contractor are generally allowable.

45. *Voluntary services.* The value of voluntary services provided by sisters or other members of religious orders is allowable provided that amounts do not exceed that paid other employees for similar work. Such amounts must be identifiable in the records of the hospital as a legal obligation of the hospital. This may be reflected by an agreement between the religious order and the hospital supported by evidence of payments to the order.

[45 FR 22610, Apr. 3, 1980]

APPENDIX F TO PART 74—[RESERVED]

APPENDIX G—ATTACHMENT O, "PROCUREMENT STANDARDS," OF OMB CIRCULAR A-102, "UNIFORM ADMINISTRATIVE REQUIREMENTS FOR GRANTS-IN-AID TO STATE AND LOCAL GOVERNMENTS"

1. *Applicability.*

a. This Attachment establishes standards and guidelines for the procurement of supplies, equipment, construction, and services for Federal assistance programs. These standards are furnished to ensure that such materials and services are obtained efficiently and economically and in compliance with the provisions of applicable Federal law and Executive orders.

b. No additional procurement requirements or subordinate regulations shall be imposed upon grantees by Executive agencies unless specifically required by Federal law or Executive orders or authorized by the Administrator for Federal Procurement Policy. This prohibition is not applicable to payment conditions issued in accordance with Treasury Circular 1075, individual grantee requirements pursuant to section 10

the basic circular [1] or the provisions of
is or other OMB circulars.
c. Provisions of current subordinate re-
irements not conforming to this attach-
ent shall be rescinded by grantor agencies
less approved by the Office of Federal
ocurement Policy (OFPP).
2. *Grantee/Grantor Responsibility.*
a. These standards do not relieve the
antee of any contractual responsibilities
der its contracts. The grantee is responsi-
e, in accordance with good administrative
actice and sound business judgment, for
e settlement of all contractual and admin-
rative issues arising out of procurements
tered into in support of a grant. These in-
ude but are not limited to: source evalua-
on, protests, disputes, and claims. Execu-
e agencies shall not substitute their judg-
ent for that of the grantee unless the
atter is primarily a Federal concern. Viola-
ns of law are to be referred to the local,
ate, or Federal authority having proper
risdiction.
b. Grantees shall use their own procure-
ent procedures which reflect applicable
ate and local laws and regulations, provid-
that procurements for Federal Assistance
ograms conform to the standards set
rth in this attachment and applicable
deral law.
3. *Grantee Procurement Improvement.*
Executive agencies awarding Federal
ants or other assistance which require or
ow for procurement by the recipients are
couraged to assist recipients in improving
eir procurement capabilities by providing
em with technical assistance, training,
blications, and other aid.
. *Procurement System Reviews.*
. Executive agencies are encouraged to
rform reviews of their grantees' procure-
ent systems if a continuing relationship
th the grantee is anticipated or a substan-
l amount of the Federal assistance is to
used for procurement and review of indi-
ual contracts is anticipated. The purpose
the review shall be to determine: (1)
ether a grantee's procurement system
ets the standards prescribed by this At-
hment or other criteria acceptable to the
PP, such as provisions of the model pro-
ement code for State and local govern-
nt and (2) whether the grantee's procure-
nt system should be certified by the re-
wing agency. Such a review will also give
agency an opportunity to give technical
istance to a grantee to remedy its pro-
ement system if it does not fully comply.
addition, such a review may provide a
is for deciding whether the grantee's contracts and related procurement documents should be subject to the grantor's prior approval, as provided by Section 6.

b. In conducting procurement system reviews, grantor agencies will evaluate a grantee's procurement system in terms of whether it complies with the standards prescribed by this Attachment and represents a fair, efficient and effective procurement system. To the maximum extent feasible, reviewers will rely upon State or local evaluations and analyses performed by agencies or organizations independent of the grantee contracting activity.

c. When a Federal grantor agency completes a procurement review, it shall furnish a report to the grantee, with a copy to OFPP.

d. All agencies should normally rely upon the resultant findings or certification for a period of 24 months before another review is performed.

e. Reviews shall be conducted in accordance with standards and guidelines approved or issued by OFPP.

f. The reviews authorized by Section 6 are waived if a grantee's procurement system is certified.

5. *Protest Procedures.*

Grantor agencies may develop an administrative procedure to handle complaints or protests regarding grantee contractor selection actions. The procedure shall be limited as follows:

a. No protest shall be accepted by the grantor agency until all administrative remedies at the grantee level have been exhausted.

b. Review is limited to:

(i) Violations of Federal law or regulations. Violations of State or local law shall be under the jurisdiction of State or local authorities.

(ii) Violations of grantee's protest procedures or failure to review a complaint or protest.

6. *Grantor Review of Proposed Contracts.*

Federal grantor pre-award review and approval of the grantee's proposed contracts and related procurement documents, such as requests for proposals and invitations for bids, is permitted only under the following circumstances:

a. The procurement is expected to exceed $10,000 and is to be awarded without competition or only one bid or offer is received in response to solicitation.

b. The procurement expected to exceed $10,000 specifies a "brand name" product; or

c. The grantee's procurement procedures or operation fails to comply with one or more significant aspects of this Attachment. The grantor agency shall notify the grantee in writing, with a copy of such notification to the OFPP.

7. *Code of Conduct.*

For HHS grants and subgrants, the re-
rements referred to are those issued
der 45 CFR 74.7, "Special grant or sub-
nt conditions."

Grantees shall maintain a written code or standards of conduct which shall govern the performance of their officers, employees or agents engaged in the award and administration of contracts supported by Federal funds. No employee, officer or agent of the grantee shall participate in selection, or in the award or administration of a contract supported by Federal funds if a conflict of interest, real or apparent, would be involved. Such a conflict would arise when:

a. The employee, officer or agent;

b. Any member of his immediate family;

c. His or her partner; or

d. An organization which employs, or is about to employ, any of the above, has a financial or other interest in the firm selected for award.

The grantee's officers, employees or agents shall neither solicit nor accept gratuities, favors or anything of monetary value from contractors, potential contractors, or parties to subagreements.

Grantees may set minimum rules where the financial interest is not substantial or the gift is an unsolicited item of nominal intrinsic value.

To the extent permitted by State or local law or regulations, such standards of conduct shall provide for penalties, sanctions, or other disciplinary actions for violations of such standards by the grantee's officers, employees, or agents, or by contractors or their agents.

8. *Procurement Procedures.*

The grantee shall establish procurement procedures which provide that proposed procurement actions shall be reviewed by grantee officials to avoid the purchase of unnecessary or duplicative items. Consideration should be given to consolidation or breaking out to obtain a more economical purchase. Where appropriate, an analysis shall be made of lease versus purchase alternatives, and any other appropriate analysis to determine which approach would be the most economical. To foster greater economy and efficiency grantees are encouraged to enter into State and local intergovernmental agreements for procurement or use of common goods and services.

9. *Contracting With Small and Minority Firms, Women's Business Enterprise and Labor Surplus Area Firms.*

a. It is national policy to award a fair share of contracts to small and minority business firms. Accordingly, affirmative steps must be taken to assure that small and minority businesses are utilized when possible as sources of supplies, equipment, construction and services. Affirmative steps shall include the following:

(1) Including qualified small and minority businesses on solicitation lists.

(2) Assuring that small and minority businesses are solicited whenever they are potential sources.

(3) When economically feasible, dividing total requirements into smaller tasks or quantities so as to permit maximum small and minority business participation.

(4) Where the requirement permits, establishing delivery schedules which will encourage participation by small and minority business.

(5) Using the services and assistance of the Small Business Administration, the Office of Minority Business Enterprise of the Department of Commerce and the Community Services Administration as required.[3]

(6) If any subcontracts are to be let, requiring the prime contractor to take the affirmative steps in 1 through 5 above.

b. Grantees shall take similar appropriate affirmative action in support of women's business enterprises.

c. Grantees are encouraged to procure goods and services from labor surplus areas.

d. Grantor agencies may impose additional regulations and requirements in the foregoing areas only to the extent specifically mandated by statute or presidential direction.

10. *Selection Procedures.*

a. All procurement transactions, regardless of whether by sealed bids or by negotiation and without regard to dollar value, shall be conducted in a manner that provides maximum open and free competition consistent with this attachment. Procurement procedures shall not restrict or eliminate competition. Examples of what is considered to be restrictive of competition include, but are not limited to: (1) placing unreasonable requirements on firms in order for them to qualify to do business, (2) noncompetitive practices between firms, (3) organizational conflicts of interest, and (4) unnecessary experience and bonding requirements.

b. The grantee shall have written selection procedures which shall provide, as a minimum, the following procedural requirements:

(1) Solicitations of offers, whether by competitive sealed bids or competitive negotiation, shall:

(a) Incorporate a clear and accurate description of the technical requirements for the material, product, or service to be pro-

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[3] Additional advice and assistance regarding the use of small or minority businesses may be obtained from the following HHS components:

1. The Office of Facilities Engineering and its regional offices (for assistance in identifying minority-owned firms interested in performing construction, alteration, or renovation work).

2. The Office of Grants and Procurement

cured. Such description shall not, in competitive procurements, contain features which unduly restrict competition. The description may include a statement of the qualitative nature of the material, product or service to be procured, and when necessary, shall set forth those minimum essential characteristics and standards to which it must conform if it is to satisfy its intended use. Detailed product specifications should be avoided if at all possible. When it is impractical or uneconomical to make a clear and accurate description of the technical requirements, a "brand name or equal" description may be used as a means to define the performance or other salient requirements of a procurement. The specific features of the named brand which must be met by offerors shall be clearly stated.

(b) Clearly set forth all requirements which offerors must fulfill and all other factors to be used in evaluating bids or proposals.

(2) Awards shall be made only to responsible contractors that possess the potential ability to perform successfully under the terms and conditions of a proposed procurement. Consideration shall be given to such matters as contractor integrity, compliance with public policy, record of past performance, and financial and technical resources.

11. *Method of Procurement.*

Procurement under grants shall be made by one of the following methods, as described herein: (a) Small purchase procedures; (b) competitive sealed bids (formal advertising); (c) competitive negotiation; (d) noncompetitive negotiation.

a. Small purchase procedures are those relatively simple and informal procurement methods that are sound and appropriate for a procurement of services, supplies or other property, costing in the aggregate not more than $10,000. Grantees shall comply with State or local small purchase dollar limits under $10,000. If small purchase procedures are used for a procurement under a grant, price or rate quotations shall be obtained from an adequate number of qualified sources.

b. In competitive sealed bids (formal advertising), sealed bids are publicly solicited and a firm-fixed-price contract (lump sum or unit price) is awarded to the responsible bidder whose bid, conforming with all the material terms and conditions of the invitation for bids, is lowest in price.

(1) In order for formal advertising to be feasible, appropriate conditions must be present, including, as a minimum, the following:

(a) A complete, adequate and realistic specification or purchase description is available.

(b) Two or more responsible suppliers are willing and able to compete effectively for the grantee's business.

(c) The procurement lends itself to a firm-fixed-price contract, and selection of the successful bidder can appropriately be made principally on the basis of price.

(2) If formal advertising is used for a procurement under a grant, the following requirements shall apply:

(a) A sufficient time prior to the date set for opening of bids, bids shall be solicited from an adequate number of known suppliers. In addition, the invitation shall be publicly advertised.

(b) The invitation for bids, including specifications and pertinent attachments, shall clearly define the items or services needed in order for the bidders to properly respond to the invitation.

(c) All bids shall be opened publicly at the time and place stated in the invitation for bids.

(d) A firm-fixed-price contract award shall be made by written notice to that responsible bidder whose bid, conforming to the invitation for bids, is lowest. Where specified in the bidding documents, factors such as discounts, transportation costs and life cycle costs shall be considered in determining which bid is lowest. Payment discounts may only be used to determine low bid when prior experience of the Grantee indicates that such discounts are generally taken.

(e) Any or all bids may be rejected when there are sound documented business reasons in the best interest of the program.

c. In competitive negotiation, proposals are requested from a number of sources and the Request for Proposal is publicized, negotiations are normally conducted with more than one of the sources submitting offers, and either a fixed-price or cost-reimbursable type contract is awarded, as appropriate. Competitive negotiation may be used if conditions are not appropriate for the use of formal advertising. If competitive negotiation is used for a procurement under a grant, the following requirements shall apply:

(1) Proposals shall be solicited from an adequate number of qualified sources to permit reasonable competition consistent with the nature and requirements of the procurement. The Request for Proposals shall be publicized and reasonable requests by other sources to compete shall be honored to the maximum extent practicable.

(2) The request for proposal shall identify all significant evaluation factors, including price or cost where required and their relative importance.

(3) The grantee shall provide mechanisms for technical evaluation of the proposals received, determinations of responsible offerors for the purpose of written or oral discussions, and selection for contract award.

(4) Award may be made to the responsible offeror whose proposal will be most advan-

tageous to the procuring party, price and other factors considered. Unsuccessful offerors should be notified promptly.

(5) Grantees may utilize competitive negotiation procedures for procurement of Architectural/Engineering professional services, whereby competitors' qualifications are evaluated and the most qualified competitor is selected, subject to negotiation of fair and reasonable compensation.

d. Noncompetitive negotiation is procurement through solicitation of a proposal from only one source, or after solicitation of a number of sources, competition is determined inadequate. Noncompetitive negotiation may be used when the award of a contract is infeasible under small purchase, competitive bidding (formal advertising) or competitive negotiation procedures. Circumstances under which a contract may be awarded by noncompetitive negotiation are limited to the following:

(1) The item is available only from a single source;

(2) Public exigency or emergency when the urgency for the requirement will not permit a delay incident to competitive solicitation;

(3) The Federal grantor agency authorizes noncompetitive negotiation; or

(4) After solicitation of a number of sources, competition is determined inadequate.

e. Additional innovative procurement methods may be used by Grantees with the approval of the Grantor Agency. A copy of such approval shall be sent to OFPP.

12. *Contract Pricing.*

The cost plus a percentage of cost and percentage of construction cost method of contracting shall not be used. Grantees shall perform some form of cost or price analysis in connection with every procurement action including contract modifications. Costs or prices based on estimated costs for contracts under grants shall be allowed only to the extent that costs incurred or cost estimates included in negotiated prices are consistent with Federal cost principles.

13. *Grantee Procurement Records.*

Grantees shall maintain records sufficient to detail the significant history of a procurement. These records shall include, but are not necessarily limited to, information pertinent to the following: rationale for the method of procurement, selection of contract type, contractor selection or rejection, and the basis for the cost or price.

14. *Contract Provisions.*

In addition to provisions defining a sound and complete procurement contract, any recipient of Federal grant funds shall include the following contract provisions or conditions in all procurement contracts and subcontracts as required by the provision, Federal Law or the Grantor Agency.

a. Contracts other than small purchases shall contain provisions or conditions which will allow for administrative, contractual, or legal remedies in instances where contractors violate or breach contract terms, and provide for such sanctions and penalties as may be appropriate.

b. All contracts in excess of $10,000 shall contain suitable provisions for termination by the grantee including the manner by which it will be effected and the basis for settlement. In addition, such contracts shall describe conditions under which the contract may be terminated for default as well as conditions where the contract may be terminated because of circumstances beyond the control of the contractor.

c. All contracts awarded in excess of $10,000 by grantees and their contractors or subgrantees shall contain a provision requiring compliance with Executive Order 11246, entitled "Equal Employment Opportunity," as amended by Executive Order 11375, and as supplemented in Department of Labor regulations (41 CFR Part 60).

d. All contracts and subgrants for *construction* or repair shall include a provision for compliance with the Copeland "Anti-Kickback" Act (18 U.S.C. 874) as supplemented in Department of Labor regulations (29 CFR, Part 3). This Act provides that each contractor or subgrantee shall be prohibited from inducing, by any means, any person employed in the construction, completion, or repair of public work, to give up any part of the compensation to which he is otherwise entitled. The grantee shall report all suspected or reported violations to the grantor agency.

e. When required by the Federal grant program legislation, all *construction* contracts in excess of $2,000 awarded by grantees and subgrantees shall include a provision for compliance with the Davis-Bacon Act (40 U.S.C. 276a to a-7) as supplemented by Department of Labor regulations (29 CFR Part 5). Under this Act contractors shall be required to pay wages to laborers and mechanics at a rate not less than the minimum wages specified in a wage determination made by the Secretary of Labor. In addition, contractors shall be required to pay wages not less often than once a week. The grantee shall place a copy of the current prevailing wage determination issued by the Department of Labor in each solicitation and the award of a contract shall be conditioned upon the acceptance of the wage determination. The grantee shall report all suspected or reported violations to the grantor agency.

f. Where applicable, all contracts awarded by grantees and subgrantees in excess of $2,000 for *construction* contracts and in excess of $2,500 for other contracts which involve the employment of mechanics or la-

orers shall include a provision for compli-
nce with sections 103 and 107 of the Con-
ract Work Hours and Safety Standards Act
0 U.S.C. 327-330) as supplemented by De-
artment of Labor regulations (29 CFR,
art 5). Under section 103 of the Act, each
ontractor shall be required to compute the
ages of every mechanic and laborer on the
asis of a standard work day of 8 hours and
standard work week of 40 hours. Work in
xcess of the standard workday or work-
eek is permissible provided that the
orker is compensated at a rate of not less
han 1½ times the basic rate of pay for all
ours worked in excess of 8 hours in any
alendar day or 40 hours in the work week.
ection 107 of the Act is applicable to con-
ruction work and provides that no laborer
mechanic shall be required to work in
rroundings or under working conditions
hich are unsanitary, hazardous, or danger-
s to his health and safety as determined
nder construction, safety and health stand-
ds promulgated by the Secretary of
abor. These requirements do not apply to
e purchases of supplies or materials or ar-
cles ordinarily available on the open
arket, or contracts for transportation or
ansmission of intelligence.

g. The contract shall include notice of
antor agency requirements and regula-
ons pertaining to reporting and patent
ghts under any contract involving re-
arch, developmental, experimental or
monstration work with respect to any dis-
very or invention which arises or is devel-
ed in the course of or under such con-
act, and of grantor agency requirements
d regulations pertaining to copyrights
d rights in data.[3]

h. All negotiated contracts (except those
arded by small purchases procedures)
arded by grantees shall include a provi-
n to the effect that the grantee, the Fed-
l grantor agency, the Comptroller Gener-
of the United States, or any of their duly
thorized representatives, shall have
cess to any books, documents, papers, and
cords of the contractor which are directly
rtinent to that specific contract, for the purpose of making audit, examination, excerpts, and transcriptions.

Grantees shall require contractors to maintain all required records for three years after grantees make final payments and all other pending matters are closed.[4]

i. Contracts, subcontracts, and subgrants of amounts in excess of $100,000 shall contain a provision which requires compliance with all applicable standards, orders, or requirements issued under Section 306 of the Clean Air Act (42 U.S.C. 1857(h)), Section 508 of the Clean Water Act (33 U.S.C. 1368), Executive Order 11738, and Environmental Protection Agency regulations (40 CFR Part 15), which prohibit the use under nonexempt Federal contracts, grants or loans of facilities included on the EPA List of Violating Facilities. The provision shall require reporting of violations to the grantor agency and to the U.S.E.P.A. Assistant Administrator for Enforcement (EN-329).

j. Contracts shall recognize mandatory standards and policies relating to energy efficiency which are contained in the State energy conservation plan issued in compliance with the Energy Policy and Conservation Act (Pub. L. 94-165).

Grantor Agencies are permitted to require changes, remedies, changed conditions, access and record retention and suspension of work clauses approved by the Office of Federal Procurement Policy.

15. *Contract Administration.*

Grantees shall maintain a contract administration system insuring that contractors perform in accordance with the terms, conditions, and specifications of their contracts or purchase orders.

[45 FR 37668, June 3, 1980; 45 FR 38380, June 9, 1980]

APPENDIX H TO PART 74—ATTACHMENT O, "PROCUREMENT STANDARDS," OF OMB CIRCULAR A-110, "GRANTS AND AGREEMENTS WITH INSTITUTIONS OF HIGHER EDUCATION, HOSPITALS, AND OTHER NONPROFIT ORGANIZATIONS"

1. This attachment provides standards for use by recipients in establishing procedures for the procurement of supplies, equipment construction and other services with Federal funds.[1] These standards are furnished to

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[3] HHS Department-wide provisions on in-
ntions and patents arising out of activities
isted by a grant are in 45 CFR Parts 6
d 8. Department-wide provisions on copy-
hts under grants and subgrants are in 45
R Part 74, Subpart O. Other provisions
these topics or on rights to data may be
other terms of a grant. If any contract
y give rise to works, inventions, patents,
data subject to any of these provisions,
e recipient shall place a requirement in
e contract for contractor and subcontrac-
compliance with the provisions. The re-
ient need not place requirements of this
d in all contracts.

[4] For clarification of paragraph 14.h as it applies to HHS grants and subgrants, see 45 CFR 74.164.

[1] For the applicability of this attachment under HHS grants and subgrants, see 45 CFR 74.160 and 74.161.

ensure that such materials and services are obtained in an effective manner and in compliance with the provisions of applicable Federal law and executive orders. No additional procurement standards or requirements shall be imposed by the Federal sponsoring agencies upon recipients unless specifically required by Federal statute or executive orders.

2. The standards contained in this attachment do not relieve the recipient of the contractual responsibilities arising under its contracts. The recipient is the responsible authority, without recourse to the Federal sponsoring agency regarding the settlement and satisfaction of all contractual and administrative issues arising out of procurements entered into, in support of a grant or other agreement. This includes disputes, claims, protests of award, source evaluation or other matters of a contractual nature. Matters concerning violation of law are to be referred to such local, State or Federal authority as may have proper jurisdiction.

3. Recipients may use their own procurement policies and procedures. However, all recipients shall adhere to the standards set forth in paragraphs 3 and 4.

a. The recipient shall maintain a code or standards of conduct that shall govern the performance of its officers, employees or agents engaged in the awarding and administration of contracts using Federal funds. No employee, officer or agent shall participate in the selection, award or administration of a contract in which Federal funds are used, where, to his knowledge, he or his immediate family, partners, or organization in which he or his immediate family or partner has a financial interest or with whom he is negotiating or has any arrangement concerning prospective employment. The recipients' officers, employees or agents shall neither solicit nor accept gratuities, favors or anything of monetary value from contractors or potential contractors. Such standards shall provide for disciplinary actions to be applied for violations of such standards by the recipients' officers, employees or agents.

b. All procurement transactions shall be conducted in a manner to provide, to the maximum extent practical, open and free competition. The recipient should be alert to organizational conflicts of interest or noncompetitive practices among contractors that may restrict or eliminate competition or otherwise restrain trade. In order to ensure objective contractor performance and eliminate unfair competitive advantage, contractors that develop or draft specifications, requirements, statements of work, invitations for bids and/or requests for proposals should be excluded from competing for such procurements.[2] Awards shall be made to the bidder/offeror whose bid/offer is responsive to the solicitation and is most advantageous to the recipient, price and other factors considered. Solicitations shall clearly set forth all requirements that the bidder/offeror must fulfill in order for his bid/offer to be evaluated by the recipient. Any and all bids/offers may be rejected when it is in the recipient's interest to do so.

c. All recipients shall establish procurement procedures that provide for, at a minimum, the following procedural requirements.

(1) Proposed procurement actions shall follow a procedure to assure the avoidance of purchasing unnecessary or duplicative items. Where appropriate, an analysis shall be made of lease and purchase, alternatives to determine which would be the most economical, practical procurement.

(2) Solicitations for goods and services shall be based upon a clear and accurate description of the technical requirements for the material, product or service to be procured. Such a description shall not, in competitive procurements, contain features which unduly restrict competition. "Brand name or equal" descriptions may be used as a means to define the performance or other salient requirements of a procurement, and when so used the specific features of the named brand which must be met by bidders/offerors shall be clearly specified.

(3) Positive efforts shall be made by the recipients to utilize small business and minority-owned business sources of supplies and services. Such efforts should allow these sources the maximum feasible opportunity to compete for contracts utilizing Federal funds.[3]

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[2] HHS granting agencies have been authorized by OMB to waive this requirement for a particular procurement upon request of the recipient making the procurement.

[3] Advice and assistance regarding the use of small or minority businesses may be obtained from the following organizations:

1. The Small Business Administration and its field offices.

2. The Office of Minority Business Enterprise, Department of Commerce.

3. The Community Services Administration.

4. The Office of Facilities Engineering, HHS, and its regional offices (for assistance in identifying minority-owned firms interested in performing construction, alteration or renovation work).

5. The Office of Grants and Procurement, HHS.

(4) The type of procuring instruments
sed, e.g., fixed price contracts, cost reim-
ursable contracts, purchase orders, incen-
ive contracts, shall be determined by the
ecipient but must be appropriate for the
articular procurement and for promoting
he best interest of the program involved.
he "cost-plus-a-percentage-of-cost"
ethod of contracting shall not be used.

(5) Contracts shall be made only with re-
ponsible contractors who possess the po-
entional ability to perform successfully
nder the terms and conditions of a pro-
osed procurement. Consideration shall be
iven to such matters as contractor integri-
y, record of past performance, financial
nd technical resources or accessibility to
ther necessary resources.

(6) All proposed sole source contracts or
here only one bid or proposal is received in
hich the aggregate expenditure is expect-
d to exceed $5,000 shall be subject to prior
pproval at the discretion of the Federal
ponsoring agency.

(7) Some form of price or cost analysis
hould be made in connection with every
rocurement action. Price analysis may be
ccomplished in various ways, including the
omparison of price quotations submitted,
arket prices and similar indicia, together
ith discounts. Cost analysis is the review
nd evaluation of each element of cost to
etermine reasonableness, allocability and
llowability.

(8) Procurement records and files for pur-
hases in excess of $10,000 shall include the
ollowing:

(a) Basis for contractor selection;

(b) Justification for lack of competition
hen competitive bids or offers are not ob-
ained;

(c) Basis for award cost or price.

(9) A system for contract administration
hall be maintained to ensure contractor
onformance with terms, conditions and
pecifications of the contract, and to ensure
dequate and timely followup of all pur-
hases.

4. The recipient shall include, in addition
provisions to define a sound and complete
greement, the following provisions in all
ntracts. These provisions shall also be ap-
lied to subcontracts.

a. Contracts in excess of $10,000 shall con-
in contractual provisions or conditions
at will allow for administrative, contrac-
al or legal remedies in instances in which
ntractors violate or breach contract
rms, and provide for such remedial actions
may be appropriate.

b. All contracts in excess of $10,000 shall
ntain suitable provisions for termination
the recipient including the manner by
hich termination will be effected and the
sis for settlement. In addition, such con-
acts shall describe conditions under which
e contract may be terminated for default as well as conditions where the contract may be terminated because of circumstances beyond the control of the contractor.

c. In all contracts for construction or facility improvement awarded for more than $100,000, recipients shall observe the bonding requirements provided in Attachment B to this circular.[4]

d. All contracts awarded by recipients and their contractors or subgrantees having a value of more than $10,000, shall contain a provision requiring compliance with Executive Order 11246, entitled "Equal Employment Opportunity," as amended by Executive Order 11375, and as supplemented in Department of Labor regulations (41 CFR, Part 60).

e. All contracts and subgrants in excess of $2,000 for construction or repair awarded by recipients and subrecipients shall include a provision for compliance with the Copeland "Anti-Kick Back" Act (18 U.S.C. 874) as supplemented in Department of Labor regulations (29 CFR, Part 3). This Act provides that each contractor or subgrantee shall be prohibited from inducing, by any means, any person employed in the construction, completion, or repair of public work, to give up any part of the compensation to which he is otherwise entitled. The recipient shall report all suspected or reported violations to the Federal sponsoring agency.

f. When required by the Federal program legislation, all construction contracts awarded by the recipients and subrecipients of more than $2,000 shall include a provision for compliance with the Davis-Bacon Act (40 U.S.C. 276a to a-7) and as supplemented by Department of Labor regulations (29 CFR, Part 5). Under this Act contractors shall be required to pay wages to laborers and mechanics at a rate not less than the minimum wages specified in a wage determination made by the Secretary of Labor. In addition, contractors shall be required to pay wages not less than once a week. The recipient shall place a copy of the current prevailing wage determination issued by the Department of Labor in each solicitation and the award of a contract shall be conditioned upon the acceptance of the wage determination. The recipient shall report all suspected or reported violations to the Federal sponsoring agency.

g. When applicable, all contracts awarded by recipients in excess of $2,000 for construction contracts and in excess of $2,500 for other contracts that involve the employment of mechanics or laborers, shall include a provision for compliance with sections 103 and 107 of the Contract Work Hours and

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[4] For HHS grants and subgrants, the requirements referred to are those in 45 CFR 74.16.

Safety Standards Act (40 U.S.C. 327-330) as supplemented by Department of Labor regulations (29 CFR, Part 5). Under section 103 of the Act, each contractor shall be required to compute the wages of every mechanic and laborer on the basis of a standard work day of 8 hours and a standard work week of 40 hours. Work in excess of the standard workday or workweek is permissible provided that the worker is compensated at a rate of not less than 1½ times the basic rate of pay for all hours worked in excess of 8 hours in any calendar day or 40 hours in the workweek. Section 107 of the Act is applicable to construction work and provides that no laborer or mechanic shall be required to work in surroundings or under working conditions which are unsanitary, hazardous or dangerous to his health and safety as determined under construction safety and health standards promulgated by the Secretary of Labor. These requirements do not apply to the purchases of supplies or materials or articles ordinarily available on the open market, or contracts for transportation or transmission of intelligence.

h. Contracts or agreements, the principal purpose of which is to create, develop or improve products, processes or methods; or for exploration into fields that directly concern public health, safety or welfare; or contracts in the field of science or technology in which there has been little significant experience outside of work funded by Federal assistance, shall contain a notice to the effect that matters regarding rights to inventions and materials generated under the contract or agreement are subject to the regulations issued by the Federal sponsoring agency and the recipient. The contractor shall be advised as to the source of additional information regarding these matters.[5]

i. All negotiated contracts (except those of $10,000 or less) awarded by recipients shall include a provision to the effect that the recipient, the Federal sponsoring agency, the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers and records of the contractor which are directly pertinent to a specific program for the purpose of making audits, examinations, excerpts and transcriptions.[6]

j. Contracts and subgrants of amounts in excess of $100,000 shall contain a provision that requires the recipient to agree to comply with all applicable standards, orders or regulations issued pursuant to the Clean Air Act of 1970 (42 U.S.C. 1857 et seq.) and the Federal Water Pollution Control Act (33 U.S.C. 1251 et seq.) as amended. Violations shall be reported to the Federal sponsoring agency and the Regional Office of the Environmental Protection Agency.

[45 FR 37671, June 3, 1980; 45 FR [illegible], June 9, 1980]

APPENDIX I TO PART 74—[RESERVED]

APPENDIX J TO PART 74—OMB CIRCULAR A-128, "AUDITS OF STATE AND LOCAL GOVERNMENTS"

Circular No. A-128

April 12, 1985.

To the Heads of Executive Departments and Establishments

Subject: Audits of State and Local Governments.

1. *Purpose.* This Circular is issued pursuant to the Single Audit Act of 1984, Pub. L. 98-502. It establishes audit requirements for State and local governments that receive Federal aid, and defines Federal responsibilities for implementing and monitoring those requirements.

2. *Supersession.* The Circular supersedes Attachment P, "Audit Requirements," of Circular A-102, "Uniform requirements for grants to State and local governments."

3. *Background.* The Single Audit Act builds upon earlier efforts to improve audits of Federal aid programs. The Act requires State or local governments that receive $100,000 or more a year in Federal funds to have an audit made for that year. Section 7505 of the Act requires the Director of the Office of Management and Budget to prescribe policies, procedures and guidelines to implement the Act. It specifies that the Director shall designate "congnizant" Federal agencies, determine criteria for making appropriate charges to Federal programs for the cost of audits, and provide procedures to assure that small firms or firms owned and controlled by disadvantaged individuals have the opportunity to participate in contracts for single audits.

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[5] HHS Department-wide provisions on inventions arising out of activities assisted by a grant are in 45 CFR Parts 6 and 8. Department-wide provisions on copyrights arising under grants and subgrants are in 45 CFR Part 74, Subpart O. Other provisions on these topics and on rights to data may be in other terms of a grant. If any contract may give rise to works, inventions, patents or data subject to these provisions, the recipient shall place a requirement in the contract for contractor and subcontractor compliance with the provisions.

[6] For clarification of this requirement as it applies to HHS grants and subgrants, see 45 CFR 74.164.

4. *Policy*. The Single Audit Act requires he following:

a. State or local governments that receive 100,000 or more a year in Federal financial sistance shall have an audit made in acordance with this Circular.

b. State or local governments that receive etween $25,000 and $100,000 a year shall ave an audit made in accordance with this ircular, or in accordance with Federal laws d regulations governing the programs hey participate in.

c. State or local governments that receive ss than $25,000 a year shall be exempt rom compliance with the Act and other ederal audit requirements. These State nd local governments shall be governed by udit requirements prescribed by State or cal law or regulation.

d. Nothing in this paragraph exempts tate or local governments from maintaing records of Federal financial assistance from providing access to such records to ederal agencies, as provided for in Federal w or in Circular A-102, "Uniform requireents for grants to state or local governents."

5. *Definitions*. For the purposes of this ircular the following definitions from the ngle Audit Act apply:

a. "Cognizant agency" means the Federal gency assigned by the Office of Management and Budget to carry out the responsilities described in paragraph 11 of this ircular.

b. "Federal finanical assistance" means asstance provided by a Federal agency in the rm of grants, contracts, cooperative agreeents, loans, loan guarantees, property, inrest subsidies, insurance, or direct approiations, but does not include direct Feder cash assistance to individuals. It includes vards received directly from Federal agens, or indirectly through other units of ates and local governments.

c. "Federal agency" has the same meaning the term 'agency' in section 551(1) of tle 5, United States Code.

d. "Generally accepted accounting princies" has the meaning specified in the genally accepted government auditing standds.

e. "Generally accepted government audit standards" means the *Standards For dit of Government Organizations, Proams, Activities, and Functions*, developed the Comptroller General, dated Febru 27, 1981.

. "Independent auditor" means:

1) A State or local government auditor o meets the independence standards ecified in generally accepted government diting standards; or

2) A public accountant who meets such dependence standards.

g. "Internal controls" means the plan of organization and methods and procedures adopted by management to ensure that:

(1) Resource use is consistent with laws, regulations, and policies;

(2) Resources are safeguarded against waste, loss, and misuse; and

(3) Reliable data are obtained, maintained, and fairly disclosed in reports.

h. "Indian tribe" means any Indian tribe, band, nations, or other organized group or community, including any Alaskan Native village or regional or village corporations (as defined in, or established under, the Alaskan Native Claims Settlement Act) that is recognized by the United States as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

i. "Local government" means any unit of local government within a State, including a county, a borough, municipality, city, town, township, parish, local public authority, special district, school district, intrastate district, council of government, and any other instrumentality of local government.

j. "Major Federal Assistance Program," as defined by Pub. L. 98-502, is described in the Attachment to this Circular.

k. "Public accountants" means those individuals who meet the qualification standards included in generally accepted government auditing standards for personnel performing government audits.

l. "State" means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands, any instrumentality thereof, and any multi-State, regional, or interstate entity that has govenmental functions and any Indian tribe.

m. "Subrecipient" means any person or government department, agency, or establishment that receives Federal financial assistance to carry out a program through a State or local government, but does not include an individual that is a beneficiary of such a program. A subreceipient may also be a direct recipient of Federal financial assistance.

6. *Scope of audit*. The Single Audit Act provides that:

a. The audit shall be made by an independent auditor in accordance with generally accepted government auditing standards covering financial and compliance audits.

b. The audit shall cover the entire operations of a State or local government or, at the option of that government, it may cover departments, agencies or establishments that received, expended, or otherwise administered Federal financial assistance during the year. However, if a State or local government receives $25,000 or more in General Revenue Sharing Funds in a fiscal year, it shall have an audit of its entire operations. A series of audits of individual departments, agencies, and establishments for the same fiscal year may be considered a single audit.

c. Public hospitals and public colleges and universities may be excluded from State and local audits and the requirements of this Circular. However, if such entities are excluded, audits of these entities shall be made in accordance with statutory requirements and the provisions of Circular A-110, "Uniform requirements for grants to universities, hospitals, and other nonprofit organizations."

d. The auditor shall determine whether:

(1) The financial statements of the government, department, agency or establishment present fairly its financial position and the results of its financial operations in accordance with generally accepted accounting principles;

(2) The organization has internal accounting and other control systems to provide reasonable assurance that it is managing Federal financial assistance programs in compliance with applicable laws and regulations; and

(3) The organization has complied with laws and regulations that may have material effect on its financial statements and on each major Federal assistance program.

7. *Frequency of audit.* Audits shall be made annually unless the State or local government has, by January 1, 1987, a constitutional or statutory requirement for less frequent audits. For those governments, the cognizant agency shall permit biennial audits, covering both years, if the government so requests. It shall also honor requests for biennial audits by governments that have an administrative policy calling for audits less frequent than annual, but only for fiscal years beginning before January 1, 1987.

8. *Internal control and compliance reviews.* The Single Audit Act requires that the independent auditor determine and report on whether the organization has internal control systems to provide reasonable assurance that it is managing Federal assistance programs in compliance with applicable laws and regulations.

a. *Internal control review.* In order to provide this assurance the auditor must make a study and evaluation of internal control systems used in administering Federal assistance programs. The study and evaluation must be made whether or not the auditor intends to place reliance on such systems. As part of this review, the auditor shall:

(1) Test whether these internal control systems are functioning in accordance with prescribed procedures.

(2) Examine the recipient's system for monitoring subrecipients and obtaining and acting on subrecipient audit reports.

b. *Compliance review.* The law also requires the auditor to determine whether the organization has complied with laws and regulations that may have a material effect on each major Federal assistance program.

(1) In order to determine which major programs are to be tested for compliance, State and local governments shall identify in their accounts all Federal funds received and expended and the programs under which they were received. This shall include funds received directly from Federal agencies and through other State and local governments.

(2) The review must include the selection and testing of a representative number of charges from each major Federal assistance program. The selection and testing of transactions shall be based on the auditor's professional judgment considering such factors as the amount of expenditures for the program and the individual awards; the newness of the program or changes in its conditions; prior experience with the program, particularly as revealed in audits and other evaluations (e.g., inspections program reviews); the extent to which the program is carried out through subrecipients; the extent to which the program contracts for goods or services; the level to which the program is already subject to program reviews or other forms of independent oversight; the adequacy of the controls for ensuring compliance; the expectation of adherence or lack of adherence to the applicable laws and regulations; and the potential impact of adverse findings.

(a) In making the test of transactions, the auditor shall determine whether:

—The amounts reported as expenditures were for allowable services, and

—The records show that those who received services or benefits were eligible to receive them.

(b) In addition to transaction testing, the auditor shall determine whether:

—Matching requirements, levels of effort and earmarking limitations were met,

—Federal financial reports and claims for advances and reimbursements contain information that is supported by the books and records from which the basic financial statements have been prepared, and

—Amounts claimed or used for matching were determined in accordance with OMB Circular A-87, "Cost principles for State and local governments," and Attachment F of Circular A-102, "Uniform requirements for grants to State and local governments."

(c) The principal compliance requirements of the largest Federal aid programs may be ascertained by referring to the *Compliance Supplement for Single Audits of State and Local Governments,* issued by OMB and available from the Government Printing Office. For those programs not covered in the Compliance Supplement, the auditor may ascertain compliance requirements by researching the statutes, regulations, and agreements governing individual programs.

(3) Transactions related to other Federal assistance programs that are selected in connection with examinations of financial statements and evaluations of internal controls shall be tested for compliance with Federal laws and regulations that apply to such transactions.

9. *Subrecipients.* State or local governments that receive Federal financial assistance and provide $25,000 or more of it in a fiscal year to a subrecipient shall:

a. Determine whether State or local subrecipients have met the audit requirements of this Circular and whether subrecipients covered by Circular A-110, "Uniform requirements for grants to universities, hospitals, and other nonprofit organizations," have met that requirement;

b. Determine whether the subrecipient spent Federal assistance funds provided in accordance with applicable laws and regulations. This may be accomplished by reviewing an audit of the subrecipient made in accordance with this Circular, Circular A-110, or through other means (e.g., program reviews) if the subrecipient has not yet had such an audit;

c. Ensure that appropriate corrective action is taken within six months after receipt of the audit report in instances of noncompliance with Federal laws and regulations;

d. Consider whether subrecipient audits necessitate adjustment of the recipient's own records; and

e. Require each subrecipient to permit independent auditors to have access to the records and financial statements as necessary to comply with this Circular.

10. *Relation to other audit requirements.* The Single Audit Act provides that an audit made in accordance with this Circular shall be in lieu of any financial or financial compliance audit required under individual Federal assistance programs. To the extent that a single audit provides Federal agencies with information and assurances they need to carry out their overall responsibilities, they shall rely upon and use such information. However, a Federal agency shall make any additional audits which are necessary to carry out its responsibilities under Federal law and regulation. Any additional Federal audit effort shall be planned and carried out in such a way as to avoid duplication.

a. The provisions of this Circular do not limit the authority of Federal agencies to make, or contract for audits and evaluations of Federal financial assistance programs, nor do they limit the authority of any Federal agency Inspector General or other Federal audit official.

b. The provisons of this Circular do not authorize any State or local government or subrecipient thereof to constrain Federal agencies, in any manner, from carrying out additional audits.

c. A Federal agency that makes or contracts for audits in addition to the audits made by recipients pursuant to this Circular shall, consistent with other applicable laws and regulations, arrange for funding the cost of such additional audits. Such additional audits include economy and efficiency audits, program results audits, and program evaluations.

11. *Cognizant agency responsiblities.* The Single Audit Act provides for cognizant Federal agencies to oversee the implementation of this Circular.

a. The Office of Management and Budget will assign cognizant agencies for States and their subdivisions and larger local governments and their subdivisions. Other Federal agencies may participate with an assigned cognizant agency, in order to fulfill the cognizance responsibilities. Smaller governments not assigned a cognizant agency will be under the general oversight of the Federal agency that provides them the most funds whether directly or indirectly.

b. A cognizant agency shall have the following responsibilities:

(1) Ensure that audits are made and reports are received in a timely manner and in accordance with the requirements of this Circular.

(2) Provide technical advice and liaison to State and local governments and independent auditors.

(3) Obtain or make quality control reviews of selected audits made by non-Federal audit organizations, and provide the results, when appropriate, to other interested organizations.

(4) Promptly inform other affected Federal agencies and appropriate Federal law enforcement officials of any reported illegal acts or irregularities. They should also inform State or local law enforcement and prosecuting authorities, if not advised by the recipient, of any violation of law within their jurisdiction.

(5) Advise the recipient of audits that have been found not to have met the requirements set forth in this Circular. In such instances, the recipient will be expected to work with the auditor to take corrective action. If corrective action is not taken, the cognizant agency shall notify the recipient and Federal awarding agencies of the facts and make recommendations for follow-up action. Major inadequacies or repetitive substandard performance of independent

auditors shall be referred to appropriate professional bodies for disciplinary action.

(6) Coordinate, to the extent practicable, audits made by or for Federal agencies that are in addition to the audits made pursuant to this Circular; so that the additional audits build upon such audits.

(7) Oversee the resolution of audit findings that affect the programs of more than one agency.

12. *Illegal acts or irregularities.* If the auditor becomes aware of illegal acts or other irregularities, prompt notice shall be given to recipient management officials above the level of involvement. (see also paragraph 13(a)(3) below for the auditor's reporting responsibilities.) The recipient, in turn, shall promptly notify the cognizant agency of the illegal acts or irregularities and of proposed and actual actions, if any. Illegal acts and irregularities include such matters as conflicts of interest, falsification of records or reports, and misappropriations of funds or other assets.

13. *Audit Reports.* Audit reports must be prepared at the completion of the audit. Reports serve many needs of State and local governments as well as meeting the requirements of the Single Audit Act.

a. The audit report shall state that the audit was made in accordance with the provisions of this Circular. The report shall be made up of at least:

(1) The auditor's report on financial statements and on a schedule of Federal assistance; the financial statements; and a schedule of Federal assistance, showing the total expenditures for each Federal assistance program as identified in the *Catalog of Federal Domestic Assistance.* Federal programs or grants that have not been assigned a catalog number shall be identified under the caption "other Federal assistance."

(2) The auditor's report on the study and evaluation of internal control systems must identify the organization's significant internal accounting controls, and those controls designed to provide reasonable assurance that Federal programs are being managed in compliance with laws and regulations. It must also identify the controls that were evaluated, the controls that were not evaluated, and the material weaknesses identified as a result of the evaluation.

(3) The auditor's report on compliance containing:

—A statement of positive assurance with respect to those items tested for compliance, including compliance with law and regulations pertaining to financial reports and claims for advances and reimbursements;

—Negative assurance on those items not tested;

—A summary of all instances of noncompliance; and

—An identification of total amounts questioned, if any, for each Federal assistance award, as a result of noncompliance.

b. The three parts of the audit report may be bound into a single report, or presented at the same time as separate documents.

c. All fraud abuse, or illegal acts or indications of such acts, including all questioned costs found as the result of these acts that auditors become aware of, should normally be covered in a separate written report submitted in accordance with paragraph 13f.

d. In addition to the audit report, the recipient shall provide comments on the findings and recommendations in the report, including a plan for corrective action taken or planned and comments on the status of corrective action taken on prior findings. If corrective action is not necessary, a statement describing the reason it is not should accompany the audit report.

e. The reports shall be made available by the State or local government for public inspection within 30 days after the completion of the audit.

f. In accordance with generally accepted government audit standards, reports shall be submitted by the auditor to the organization audited and to those requiring or arranging for the audit. In addition, the recipient shall submit copies of the reports to each Federal department or agency that provided Federal assistance funds to the recipient. Subrecipients shall submit copies to recipients that provided them Federal assistance funds. The reports shall be sent within 30 days after the completion of the audit, but no later than one year after the end of the audit period unless a longer period is agreed to with the cognizant agency.

g. Recipients of more than $100,000 in Federal funds shall submit one copy of the audit report within 30 days after issuance to a central clearinghouse to be designated by the Office of Management and Budget. The clearinghouse will keep completed audits on file and follow up with State and local governments that have not submitted required audit reports.

h. Recipients shall keep audit reports on file for three years from their issuance.

14. *Audit Resolution.* As provided in paragraph 11, the cognizant agency shall be responsible for monitoring the resolution of audit findings that affect the programs of more than one Federal agency. Resolution of findings that relate to the programs of a single Federal agency will be the responsibility of the recipient and that agency. Alternate arrangements may be made on a case-by-case basis by agreement among the agencies concerned.

Resolution shall be made within six months after receipt of the report by the Federal departments and agencies. Correc-

ve action should proceed as rapidly as pos-
ble.

15. *Audit workpapers and reports.* Work-
apers and reports shall be retained for a
inimum of three years from the date of
e audit report, unless the auditor is noti-
ed in writing by the cognizant agency to
tend the retention period. Audit work-
apers shall be made available upon request
the cognizant agency or its designee or
e General Accounting Office, at the com-
etion of the audit.

16. *Audit Costs.* The cost of audits made in
cordance with the provisions of this Cir-
lar are allowable charges to Federal as-
stance programs.

a. The charges may be considered a direct
st or an allocated indirect cost, deter-
ined in accordance with the provision of
rcular A-87, "Cost principles for State
d local governments."

b. Generally, the percentage of costs
arged to Federal assistance programs for
single audit shall not exceed the percent-
e that Federal funds expended represent
total funds expended by the recipient
ring the fiscal year. The percentage may
exceeded, however, if appropriate docu-
entation demonstrates higher actual cost.

17. *Sanctions.* The Single Audit Act pro-
des that no cost may be charged to Feder-
assistance programs for audits required
the Act that are not made in accordance
th this Circular. In cases of continued in-
lity or unwillingness to have a proper
dit, Federal agencies must consider other
propriate sanctions including:

Withholding a percentage of assistance
payments until the audit is completed sat-
isfactorily,

Withholding or disallowing overhead
costs, and

Suspending the Federal assistance agree-
ment until the audit is made.

18. *Auditor Selection.* In arranging for
dit services State and local governments
all follow the procurement standards pre-
ribed by Attachment O of Circular A-102,
niform requirements for grants to State
d local governments." The standards pro-
le that while recipients are encouraged to
ter into intergovernmental agreements
-audit and other services, analysis should
made to determine whether it would be
re economical to purchase the services
m private firms. In instances where use
such intergovernmental agreements are
quired by State statutes (e.g., audit serv-
s) these statutes will take precedence.

19. *Small and Minority Audit Firms.*
all audit firms and audit firms owned
d controlled by socially and economically
advantaged individuals shall have the
ximum practicable opportunity to par-
ipate in contracts awarded to fulfill the
quirements of this Circular. Recipients of Federal assistance shall take the following steps to further this goal:

a. Assure that small audit firms and audit firms owned and controlled by socially and economically disadvantaged individuals are used to the fullest extent practicable.

b. Make information on forthcoming opportunities available and arrange timeframes for the audit so as to encourage and facilitate participation by small audit firms and audit firms owned and controlled by socially and economically disadvantaged individuals.

c. Consider in the contract process whether firms competing for larger audits intend to subcontract with small audit firms and audit firms owned and controlled by socially and economically disadvantaged individuals.

d. Encourage contracting with small audit firms or audit firms owned and controlled by socially and economically disadvantaged individuals which have traditionally audited government programs and, in such cases where this is not possible, assure that these firms are given consideration for audit subcontrating opportunities.

e. Encourage contracting with consortiums of small audit firms as described in paragraph (a) above when a contract is too large for an individual small audit firm or audit firm owned and controlled by socially and economically disadvantaged individuals.

f. Use the services and assistance, as appropriate, of such organizations as the Small Business Administration in the solicitation and utilization of small audit firms or audit firms owned and controlled by socially and economically disadvantaged individuals.

20. *Reporting.* Each Federal agency will report to the Director of OMB on or before March 1, 1987, and annually thereafter on the effectiveness of State and local governments in carrying out the provisions of this Circular. The report must identify each State or local government or Indian tribe that, in the opinion of the agency, is failing to comply with Circular.

21. *Regulations.* Each Federal agency shall include the provisions of this Circular in its regulations implementing the Single Audit Act.

22. *Effective date.* This Circular is effective upon publication and shall apply to fiscal years of State and local governments that begin after December 31, 1984. Earlier implementation is encouraged. However, until it is implemented, the audit provisions of Attachment P to Circular A-102 shall continue to be observed.

23. *Inquiries.* All questions or inquiries should be addressed to Financial Management Division, Office of Management and Budget, telephone number 202/395-3993.

24. *Sunset review date.* This Circular shall have an independent policy review to ascer-

tain its effectiveness three years from the date of issuance.

David A. Stockman,
Director.

CIRCULAR A-128 ATTACHMENT

Definition of Major Program as Provided in Pub. L. 98-502

"Major Federal Assistance Program," for State and local governments having Federal assistance expenditures between $100,000 and $100,000,000, means any program for which Federal expenditures during the applicable year exceed the larger of $300,000, or 3 percent of such total expenditures.

Where total expenditures of Federal assistance exceed $100,000,000, the following criteria apply:

Total expenditures of Federal financial assistance for all programs		Major Federal assistance program means any program that exceeds
More than	But less than	
$100 million	1 billion	$3 million
1 billion	2 billion	4 million
2 billion	3 billion	7 million
3 billion	4 billion	10 million
4 billion	5 billion	13 million
5 billion	6 billion	16 million
6 billion	7 billion	19 million
Over 7 billion	....	20 million

[50 FR 31716, Aug. 6, 1985]

PART 75—INFORMAL GRANT APPEALS PROCEDURES

Subpart A—Indirect Cost Appeals

Sec.
75.1 Purpose.
75.2 Scope.
75.3 Definitions.
75.4 Notification.
75.5 Submission to the Regional Director.
75.6 Action by the Regional Director.

AUTHORITY: Sec. 1102, 49 Stat. 647, 42 U.S.C. 1302.

SOURCE: 47 FR 17511, Apr. 23, 1982, unless otherwise noted.

Subpart A—Indirect Cost Appeals

§ 75.1 Purpose.

This subpart establishes informal procedures for resolving disputes arising in the negotiation of indirect cost rates and certain other cost allocations (as set forth in § 75.2) that are used in determining amounts to be reimbursed under grants awarded by the Operating Divisions of the Department of Health and Human Services. A grantee must exhaust the procedures set forth in this subpart prior to appealing a disputed issue(s) to the Departmental Grants Appeals Board under Part 16 of this subtitle.

§ 75.2 Scope.

(a) This subpart applies to all disputes arising from determinations made by a Director, Division of Cost Allocation (DCA), in the Department's regional Offices including, but not limited to:

(1) Indirect cost rates negotiated with colleges and universities, State and local government agencies, hospitals, and non-profit institutions.

(2) Patient care rates and amounts associated with the care of patients participating in research programs supported by the Department.

(3) Cost allocation plans negotiated with State and local units of government other than plans provided for under paragraph (a)(5) of this section.

(4) Fringe benefit rates, computer rates or costing methodologies and other special rates negotiated with colleges and universities, State and local government agencies, hospitals, and non-profit institutions.

(5) Cost allocation plans with State public assistance agencies as described in Subpart E of 45 CFR Part 95.

(6) Disallowances by the Director, DCA, of costs as described in Subpart E of 45 CFR Part 95.

(b) Notwithstanding paragraph (a) of this section, this subpart shall not be applicable to disputed issues which are appealed to the Armed Services Board of Contract Appeals under a contract with the Department.

§ 75.3 Definitions.

For purposes of this subpart:

(a) "Grantee" means the agency institution or organization named as grantee in a grant award document issued by an Operating Division of the Department. For disputes involving cost allocation plans, this term also includes a State or local unit of government which includes an agency that is named as grantee in a grant awar document and a State agency as defined in Subpart E of 45 CFR Part 95.

(b) Other terms shall have the meaning set forth in Part 74 of this title, unless the context below indicates otherwise.

§ 75.4 Notification.

Where an agreement cannot be reached between the Director, DCA, and the grantee, the Director, DCA will promptly notify the grantee in writing of the Director's determination. This notification will set forth the reasons for the determination in sufficient detail to enable the grantee to respond and will inform the grantee of its opportunity for reconsideration under this subpart.

§ 75.5 Submission to the Regional Director.

If the grantee wishes to request reconsideration of the DCA Director's determination, it may submit an application for such reconsideration to the Regional Director. The grantee's application must be postmarked or hand delivered no later than 30 days after receipt of the notification described in § 75.4. The Regional Director, however, may grant an extension of time for submission of the application if the extension is requested and justified by the grantee. Although the application need not follow any prescribed format, it must clearly identify the issue(s) in dispute and must contain a full statement of the grantee's position on such issue(s) along with pertinent facts and reasons in support of its position.

§ 75.6 Action by the Regional Director.

(a) Upon receipt of an application for reconsideration, the Regional Director will immediately notify the grantee that its application has been received and will be acted upon as soon as possible.

(b) The Regional Director will review all background material on the issue(s). Within 30 days after receipt of the grantee's application, and with at least 10 days' written notice, the grantee will be provided the opportunity to meet with the Regional Director to discuss the issue(s) and to submit additional information in support of its position. The Regional Director may consult the DCA, other regional officials, Departmental central office officials, and other individuals in conducting the review.

(c) Within 45 days after the meeting described in § 75.6(b) (or 45 days after submission of any supplemental information provided by the grantee) the Regional Director will notify the grantee in writing of the decision, in accordance with the provisions of § 74.304 of this title. If the Regional Director's decision is adverse to the grantee's position, this notification will state the basis of the decision and will inform the grantee of its right to appeal the decision to the Departmental Grants Appeals Board under Part 16 of this title.

(d) The Regional Director may delegate the responsibilities described in this section to another senior Departmental official in his region. This delegation, however, may not be made to the Director, Regional Administrative Support Center, or to the Director, DCA.

PART 76—GOVERNMENTWIDE DEBARMENT AND SUSPENSION (NONPROCUREMENT) AND GOVERNMENTWIDE REQUIREMENTS FOR DRUG—FREE WORKPLACE (GRANTS)

Subpart A—General

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76.100 Purpose.
76.105 Definitions.
76.110 Coverage.
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Subpart B—Effect of Action

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76.205 Ineligible persons.
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APPENDIX A TO PART 76—CERTIFICATION REGARDING DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS—PRIMARY COVERED TRANSACTIONS
APPENDIX B TO PART 76—CERTIFICATION REGARDING DEBARMENT, SUSPENSION, INELIGIBILITY AND VOLUNTARY EXCLUSION—LOWER TIER COVERED TRANSACTIONS
APPENDIX C TO PART 76—CERTIFICATION REGARDING DRUG-FREE WORKPLACE REQUIREMENTS

AUTHORITY: E.O. 12549; sec. 5151-5160 of the Drug-Free Workplace Act of 1988 (Pub. L. 100-690, Title V, Subtitle D; 41 U.S.C. 701 et seq); 5 U.S.C. 301.

CROSS REFERENCE: See also Office of Management and Budget notice published at 55 FR 21679, May 25, 1990.

SOURCE: 53 FR 19200, 19204, May 26, 1988, unless otherwise noted.

EDITORIAL NOTE 1: A nomenclature change affecting this part appears at 53 FR 19200, May 26, 1988.

EDITORIAL NOTE 2: For additional information, see related documents published at 52 FR 20360, May 29, 1987, 53 FR 19160, May 26, 1988, and 53 FR 34474, September 1988.

Subpart A—General

§ 76.100 Purpose.

(a) Executive Order 12549 provides that, to the extent permitted by law, Executive departments and agencies shall participate in a governmentwide system for nonprocurement debarment and suspension. A person who is debarred or suspended shall be excluded from Federal financial and nonfinancial assistance and benefits under Federal programs and activities. Debarment or suspension of a participant in a program by one agency shall have governmentwide effect.

(b) These regulations implement section 3 of Executive Order 12549 and the guidelines promulgated by the Office of Management and Budget under section 6 of the Executive Order by:

(1) Prescribing the programs and activities that are covered by the governmentwide system;

(2) Prescribing the governmentwide criteria and governmentwide minimum due process procedures that each agency shall use;

(3) Providing for the listing of debarred and suspended participants, participants declared ineligible (see definition of "ineligible" in § 76.105(i)), and participants who have voluntarily excluded themselves from participation in covered transactions

(4) Setting forth the consequences of a debarment, suspension, determination of ineligibility, or voluntary exclusion; and

(5) Offering such other guidance as necessary for the effective implementation and administration of the governmentwide system.

(c) Although these regulations cover the listing of ineligible participants and the effect of such listing, they do not prescribe policies and procedures governing declarations of ineligibility.

§ 76.105 Definitions.

(a) "Adequate evidence". Information sufficient to support the reasonable belief that a particular act or omission has occurred.

(b) "Affiliate". Persons are affiliates of each another if, directly or indirectly, either one controls or has the power to control the other, or, a third person controls or has the power to control both. Indicia of control include, but are not limited to: interlocking management or ownership, identity of interests among family members, shared facilities and equipment, common use of employees, or a business entity organized following the suspension or debarment of a person which has the same or similar management, ownership, or principal employees as the suspended, debarred, ineligible, or voluntarily excluded person.

(c) "Agency". Any executive department, military department or defense agency or other agency of the executive branch, excluding the independent regulatory agencies.

(d) "Civil judgment". The disposition of a civil action by any court of competent jurisdiction, whether entered by verdict, decision, settlement, stipulation, or otherwise creating a civil liability for the wrongful acts complained of; or a final determination of liability under the Program Fraud Civil Remedies Act of 1988 (31 U.S.C. 3801-12).

(1) "Civil judgment" also includes determinations under the Civil Monetary Penalties Act (42 U.S.C. 1320a-7a).

(e) "Conviction". A judgment of conviction of a criminal offense by any court of competent jurisdiction, whether entered upon a verdict or a plea, including a plea of nolo contendere.

(f) "Debarment". An action taken by a debarring official in accordance with these regulations to exclude a person from participating in covered transactions. A person so excluded is "debarred."

(g) "Debarring official". An official authorized to impose debarment. The debarring official is either:

(1) The agency head, or

(2) An official designated by the agency head.

(h) "Indictment". Indictment for a criminal offense. An information or other filing by competent authority charging a criminal offense shall be given the same effect as an indictment.

(i) "Ineligible". Excluded from participation in Federal nonprocurement programs pursuant to a determination of ineligibility under statutory, executive order, or regulatory authority, other than Executive Order 12549 and its agency implementing regulations; for exemple, excluded pursuant to the Davis-Bacon Act and its implementing regulations, the equal employment opportunity acts and executive orders, or the environmental protection acts and executive orders. A person is ineligible where the determination of ineligibility affects such person's eligibility to participate in more than one covered transaction.

(j) "Legal proceedings". Any criminal proceeding or any civil judicial proceeding to which the Federal Government or a State or local government or quasi-governmental authority is a party. The term includes appeals from such proceedings.

(k) "Nonprocurement List". The portion of the *List of Parties Excluded from Federal Procurement or Nonprocurement Programs* complied, maintained and distributed by the General Services Administration (GSA) containing the names and other information about persons who have been debarred, suspended, or voluntarily excluded under Executive Order 12549 and these regulations, and those who have been determined to be ineligible.

(l) "Notice". A written communication served in person or sent by certified mail, return receipt requested, or its equivalent, to the last known address of a party, its identified counsel, its agent for service of process, or any partner, officer, director, owner, or joint venturer of the party. Notice, if undeliverable, shall be considered to have been received by the addressee five days after being properly sent to the last address known by the agency.

(m) "Participant". Any person who submits a proposal for, enters into, or reasonably may be expected to enter into a covered transaction. This term also includes any person who acts on behalf of or is authorized to commit a participant in a covered transaction as an agent or representative of another participant.

(n) "Person". Any individual, corporation, partnership, association, unit of government or legal entity, however organized, except: foreign governments or foreign governmental entities, public international organizations, foreign government owned (in whole or in part) or controlled entities, and entities consisting wholly or partially of foreign governments or foreign governmental entities.

(o) "Preponderance of the evidence". Proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

(p) "Principal". Officer, director, owner, partner, key employee, or other person within a participant with primary management or supervisory responsibilities; or a person who has a critical influence on or substantive control over a covered transaction, whether or not employed by the participant. Persons who have a critical influence on or substantive control over a covered transaction are:

(1) Principal investigators.

(2) Researchers.

(q) "Proposal". A solicited or unsolicited bid, application, request, invitation to consider or similar communication by or on behalf of a person seeking to participate or to receive a benefit, directly or indirectly, in or under a covered transaction.

(r) "Respondent". A person against whom a debarment or suspension action has been initiated.

(s) "State". Any of the States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, or any agency of a State, exclusive of institutions of higher education, hospitals, and units of local government. A State instrumentality will be considered part of the State government if it has a written determination from a State government that such State considers that instrumentality to be an agency of the State government.

(t) "Suspending official". An official authorized to impose suspension. The suspending official is either:

(1) The agency head, or

(2) An official designated by the agency head.

(u) "Suspension". An action taken by a suspending official in accordance with these regulations that immediately excludes a person from participating in covered transactions for a temporary period, pending completion of an investigation and such legal, debarment, or Program Fraud Civil Remedies Act proceedings as may ensue. A person so excluded is "suspended."

(v) "Voluntary exclusion or voluntarily excluded". A status of nonparticipation or limited participation in covered transactions assumed by a person pursuant to the terms of a settlement.

(w) "HHS". The Department of Health and Human Services.

[53 FR 19200, 19204, May 26, 1988, as amended at 53 FR 19200, May 26, 1988]

§ 76.110 Coverage.

(a) These regulations apply to all persons who have participated, are currently participating or may reasonably be expected to participate in transactions under Federal nonprocurement programs. For purposes of these regulations such transactions will be referred to as "covered transactions."

(1) *Covered transaction.* For purposes of these regulations, a covered transaction is a primary covered transaction or a lower tier covered transaction. Covered transactions at any tier need not involve the transfer of Federal funds.

(i) *Primary covered transaction.* Except as noted in paragraph (a)(2) of this section, a primary covered transaction is any nonprocurement transaction between an agency and a person, regardless of type, including: grants, cooperative agreements, scholarships, fellowships, contracts of assistance, loans, loan guarantees, subsidies, insurance, payments for specified use, donation agreements and any other nonprocurement transactions between a Federal agency and a person. Primary covered transactions also include those transactions specially designated by the U.S. Department of Housing and Urban Development in such agency's regulations governing debarment and suspension.

(ii) *Lower tier covered transaction.* A lower tier covered transaction is:

(A) Any transaction between a participant and a person other than a procurement contract for goods or services, regardless of type, under a primary covered transaction.

(B) Any procurement contract for goods or services between a participant and a person, regardless of type, expected to equal or exceed the Federal procurement small purchase threshold fixed at 10 U.S.C. 2304(g) and 41 U.S.C. 253(g) (currently $25,000) under a primary covered transaction.

(C) Any procurement contract for goods or services between a participant and a person under a covered transaction, regardless of amount, under which that person will have a critical influence on or substantive control over that covered transaction. Such persons are:

(*1*) Principal investigators.

(*2*) Providers of Federally-required audit services.

(*3*) Researchers.

(2) *Exceptions.* The following transactions are not covered:

(i) Statutory entitlements or mandatory awards (but not subtier awards thereunder which are not themselves mandatory), including deposited funds insured by the Federal Government;

(ii) Direct awards to foreign governments or public international organizations, or transactions with foreign governments or foreign governmental entities, public international organizations, foreign government owned (in whole or in part) or controlled entities, entities consisting wholly or partially of foreign governments or foreign governmental entities;

(iii) Benefits to an individual as a personal entitlement without regard to the individual's present responsibility (but benefits received in an individual's business capacity are not excepted);

(iv) Federal employment;

(v) Transactions pursuant to National or agency-recognized emergencies or disasters;

(vi) Incidental benefits derived from ordinary governmental operations; and

(vii) Other transactions where the application of these regulations would be prohibited by law.

(b) *Relationship to other sections.* This section describes the types of transactions to which a debarment or suspension under the regulations will apply. Subpart B, "Effect of Action," § 76.200, "Debarment or suspension," sets forth the consequences of a debarment or suspension. Those consequences would obtain only with respect to participants and principals in the covered transactions and activities described in § 76.110(a). Sections 76.325, "Scope of debarment," and 76.420, "Scope of suspension," govern the extent to which a specific participant or organizational elements of a participant would be automatically included within a debarment or suspension action, and the conditions under which affiliates or persons associated with a participant may also be brought within the scope of the action.

(c) *Relationship to Federal procurement activities.* Debarment and suspension of Federal procurement contractors and subcontractors under Federal procurement contracts are covered by the Federal Acquisition Regulation (FAR), 48 CFR Subpart 9.4.

[53 FR 19200, 19204, May 26, 1988, as amended at 53 FR 19200, May 26, 1988]

§ 76.115 Policy.

(a) In order to protect the public interest, it is the policy of the Federal Government to conduct business only with responsible persons. Debarment and suspension are discretionary actions that, taken in accordance with Executive Order 12549 and these regulations, are appropriate means to implement this policy.

(b) Debarment and suspension are serious actions which shall be used only in the public interest and for the Federal Government's protection and not for purposes of punishment. Agencies may impose debarment or suspension for the causes and in accordance with the procedures set forth in these regulations.

(c) When more than one agency has an interest in the proposed debarment or suspension of a person, consideration shall be given to designating one agency as the lead agency for making the decision. Agencies are encouraged to establish methods and procedures for coordinating their debarment or suspension actions.

Subpart B—Effect of Action

§ 76.200 Debarment or suspension.

(a) *Primary covered transactions.* Except to the extent prohibited by law, persons who are debarred or suspended shall be excluded from primary covered transactions as either participants or principals throughout the executive branch of the Federal Government for the period of their debarment or suspension. Accordingly, no agency shall enter into primary covered transactions with such debarred or suspended persons during such period, except as permitted pursuant to § 76.215.

(b) *Lower tier covered transactions.* Except to the extent prohibited by law, persons who have been debarred or suspended shall be excluded from participating as either participants or principals in all lower tier covered transactions (see § 76.110(a)(1)(ii)) for the period of their debarment or suspension.

(c) *Exceptions.* Debarment or suspension does not affect a person's eligibility for:

(1) Statutory entitlements or mandatory awards (but not subtier awards thereunder which are not themselves mandatory), including deposited funds insured by the Federal Government;

(2) Direct awards to foreign governments or public international organizations, or transactions with foreign governments or foreign governmental entities, public international organizations, foreign government owned (in whole or in part) or controlled entities, and entities consisting wholly or partially of foreign governments or foreign governmental entities;

(3) Benefits to an individual as a personal entitlement without regard to the individual's present responsibility (but benefits received in an individual's business capacity are not excepted);

(4) Federal employment;

(5) Transactions pursuant to National or agency-recognized emergencies or disasters;

(6) Incidental benefits derived from ordinary governmental operations; and

(7) Other transactions where the application of these regulations would be prohibited by law.

§ 76.205 Ineligible persons.

Persons who are ineligible, as defined in § 76.105(i), are excluded in accordance with the applicable statutory, executive order, or regulatory authority.

§ 76.210 Voluntary exclusion.

Persons who accept voluntary exclusions under § 76.315 are excluded in accordance with the terms of their settlements. HHS shall, and participants may, contact the original action agency to ascertain the extent of the exclusion.

§ 76.215 Exception provision.

HHS may grant an exception permitting a debarred, suspended, or voluntarily excluded person to participate in a particular covered transaction upon a written determination by the agency head or an authorized designee stating the reason(s) for deviating from the Presidential policy established by Executive Order 12549 and § 76.200 of this rule. However, in accordance with the President's stated intention in the Executive Order, exceptions shall be granted only infrequently. Exceptions shall be reported in accordance with § 76.505(a).

§ 76.220 Continuation of covered transactions.

(a) Notwithstanding the debarment, suspension, determination of ineligibility, or voluntary exclusion of any person by an agency, agencies and participants may continue covered transactions in existence at the time the person was debarred, suspended, declared ineligible, or voluntarily excluded. A decision as to the type of termination action, if any, to be taken should be made only after thorough review to ensure the propriety of the proposed action.

(b) Agencies and participants shall not renew or extend covered transactions (other than no-cost time extensions) with any person who is debarred, suspended, ineligible, or voluntarily excluded, except as provided in § 76.215.

§ 76.225 Failure to adhere to restrictions.

Except as permitted under § 76.215 or § 76.220 of these regulations, a participant shall not knowingly do business under a covered transaction with a person who is debarred or suspended, or with a person who is ineligible for or voluntarily excluded from that covered transaction. Violation of this restriction may result in disallowance of costs, annulment or termination of award, issuance of a stop work order, debarment or suspension, or other remedies, as appropriate. A participant may rely upon the certification of a prospective participant in a lower tier covered transaction that it and its principals are not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction (see Appendix B), unless it knows that the certification is erroneous. An agency has the burden of proof that such participant did knowingly do business with such a person.

Subpart C—Debarment

§ 76.300 General.

The debarring official may debar a person for any of the causes in § 76.305, using procedures established in §§ 76.310 through 76.314. The existence of a cause for debarment, however, does not necessarily require that the person be debarred; the seriousness of the person's acts or omissions and any mitigating factors shall be considered in making any debarment decision.

§ 76.305 Causes for debarment.

Debarment may be imposed in accordance with the provisions of §§ 76.300 through 76.314 for:

(a) Conviction of or civil judgment for:

(1) Commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public or private agreement or transaction;

(2) Violation of Federal or State antitrust statutes, including those proscribing price fixing between competitors, allocation of customers between competitors, and bid rigging;

(3) Commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, receiving stolen property, making false claims, or obstruction of justice; or

(4) Commission of any other offense indicating a lack of business integrity or business honesty that seriously and directly affects the present responsibility of a person.

(b) Violation of the terms of a public agreement or transaction so serious as to affect the integrity of an agency program, such as:

(1) A willful failure to perform in accordance with the terms of one or more public agreements or transactions;

(2) A history of failure to perform or of unsatisfactory performance of one or more public agreements or transactions; or

(3) A willful violation of a statutory or regulatory provision or requirement applicable to a public agreement or transaction.

(c) Any of the following causes:

(1) A nonprocurement debarment by any Federal agency taken before October 1, 1988, the effective date of these regulations, or a procurement debarment by any Federal agency taken pursuant to 48 CFR Subpart 9.4;

(2) Knowingly doing business with a debarred, suspended, ineligible, or voluntarily excluded person, in connection with a covered transaction, except as permitted in § 76.215 or § 76.220;

(3) Failure to pay a single substantial debt, or a number of outstanding debts (including disallowed costs and overpayments, but not including sums owed the Federal Government under the Internal Revenue Code) owed to any Federal agency or instrumentality, provided the debt is uncontested by the debtor or, if contested, provided that the debtor's legal and administrative remedies have been exhausted;

(4) Violation of a material provision of a voluntary exclusion agreement

entered into under § 76.315 or of any settlement of a debarment or suspension action; or

(5) Violation of any requirement of Subpart F of this part, relating to providing a drug-free workplace, as set forth in § 76.615 of this part.

(d) Any other cause of so serious or compelling a nature that it affects the present responsibility of a person.

[53 FR 19200, 19204, May 26, 1988, as amended at 54 FR 4950, 4963, Jan. 31, 1989; 55 FR 21702, May 25, 1990]

§ 76.310 Procedures.

HHS shall process debarment actions as informally as practicable, consistent with the principles of fundamental fairness, using the procedures in §§ 76.311 through 76.314.

§ 76.311 Investigation and referral.

Information concerning the existence of a cause for debarment from any source shall be promptly reported, investigated, and referred, when appropriate, to the debarring official for consideration. After consideration, the debarring official may issue a notice of proposed debarment.

§ 76.312 Notice of proposed debarment.

A debarment proceeding shall be initiated by notice to the respondent advising:

(a) That debarment is being considered;

(b) Of the reasons for the proposed debarment in terms sufficient to put the respondent on notice of the conduct or transaction(s) upon which it is based;

(c) Of the cause(s) relied upon under § 76.305 for proposing debarment;

(d) Of the provisions of § 76.311 through § 76.314, and any other HHS procedures, if applicable, governing debarment decisionmaking; and

(e) Of the potential effect of a debarment.

§ 76.313 Opportunity to contest proposed debarment.

(a) *Submission in opposition.* Within 30 days after receipt of the notice of proposed debarment, the respondent may submit, in person, in writing, or through a representative, information and argument in opposition to the proposed debarment.

(b) *Additional proceedings as to disputed material facts.*

(1) In actions not based upon a conviction or civil judgment, if the debarring official finds that the respondent's submission in opposition raises a genuine dispute over facts material to the proposed debarment, respondent(s) shall be afforded an opportunity to appear with a representative, submit documentary evidence, present witnesses, and confront any witness the agency presents.

(2) A transcribed record of any additional proceedings shall be made available at cost to the respondent, upon request, unless the respondent and the agency, by mutual agreement, waive the requirement for a transcript.

§ 76.314 Debarring official's decision.

(a) *No additional proceedings necessary.* In actions based upon a conviction or civil judgment, or in which there is no genuine dispute over material facts, the debarring official shall make a decision on the basis of all the information in the administrative record, including any submission made by the respondent. The decision shall be made within 45 days after receipt of any information and argument submitted by the respondent, unless the debarring official extends this period for good cause.

(b) *Additional proceedings necessary.*

(1) In actions in which additional proceedings are necessary to determine disputed material facts, written findings of fact shall be prepared. The debarring official shall base the decision on the facts as found, together with any information and argument submitted by the respondent and any other information in the administrative record.

(2) The debarring official may refer disputed material facts to another official for findings of fact. The debarring official may reject any such findings, in whole or in part, only after specifically determining them to be arbitrary and capricious or clearly erroneous.

(3) The debarring official's decision shall be made after the conclusion of the proceedings with respect to disputed facts.

(c) *Standard of proof.*

(1) In any debarment action, the cause for debarment must be established by a preponderance of the evidence. Where the proposed debarment is based upon a conviction or civil judgment, the standard shall be deemed to have been met.

(2) *Burden of proof.* The burden of proof is on the agency proposing debarment.

(d) *Notice of debarring official's decision.* (1) If the debarring official decides to impose debarment, the respondent shall be given prompt notice:

(i) Referring to the notice of proposed debarment;

(ii) Specifying the reasons for debarment;

(iii) Stating the period of debarment, including effective dates; and

(iv) Advising that the debarment is effective for covered transactions throughout the executive branch of the Federal Government unless an agency head or an authorized designee makes the determination referred to in § 76.215.

(2) If the debarring official decides not to impose debarment, the respondent shall be given prompt notice of that decision. A decision not to impose debarment shall be without prejudice to a subsequent imposition of debarment by any other agency.

§ 76.315 Settlement and voluntary exclusion.

(a) When in the best interest of the Government, HHS may, at any time, settle a debarment or suspension action.

(b) If a participant and the agency agree to a voluntary exclusion of the participant, such voluntary exclusion shall be entered on the Nonprocurement List (see Subpart E).

§ 76.320 Period of debarment.

(a) Debarment shall be for a period commensurate with the seriousness of the cause(s). If a suspension precedes a debarment, the suspension period shall be considered in determining the debarment period.

(1) Debarment for causes other than those related to a violation of the requirements of Subpart F of this part generally should not exceed three years. Where circumstances warrant, a longer period of debarment may be imposed.

(2) In the case of a debarment for a violation of the requirements of Subpart F of this part (*see* § 76.305(c)(5)), the period of debarment shall not exceed five years.

(b) The debarring official may extend an existing debarment for an additional period, if that official determines that an extension is necessary to protect the public interest. However, a debarment may not be extended solely on the basis of the facts and circumstances upon which the initial debarment action was based. If debarment for an additional period is determined to be necessary, the procedures of §§ 76.311 through 76.314 shall be followed to extend the debarment.

(c) The respondent may request the debarring official to reverse the debarment decision or to reduce the period or scope of debarment. Such a request shall be in writing and supported by documentation. The debarring official may grant such a request for reasons including, but not limited to:

(1) Newly discovered material evidence;

(2) Reversal of the conviction or civil judgment upon which the debarment was based;

(3) Bona fide change in ownership or management;

(4) Elimination of other causes for which the debarment was imposed; or

(5) Other reasons the debarring official deems appropriate.

[53 FR 19200, 19204, May 26, 1988, as amended at 54 FR 4950, 4963, Jan. 31, 1989; 55 FR 21702, May 25, 1990]

§ 76.325 Scope of debarment.

(a) *Scope in general.* (1) Debarment of a person under these regulations constitutes debarment of all its divisions and other organizational elements from all covered transactions, unless the debarment decision is limited by its terms to one or more specifically identified individuals, divisions or other organizational elements or to specific types of transactions.

(2) The debarment action may include any affiliate of the participant that is specifically named and given notice of the proposed debarment and an opportunity to respond (see §§ 76.311 through 76.314).

(b) *Imputing conduct.* For purposes of determining the scope of debarment, conduct may be imputed as follows:

(1) *Conduct imputed to participant.* The fraudulent, criminal or other seriously improper conduct of any officer, director, shareholder, partner, employee, or other individual associated with a participant may be imputed to the participant when the conduct occurred in connection with the individual's performance of duties for or on behalf of the participant, or with the participant's knowledge, approval, or acquiescence. The participant's acceptance of the benefits derived from the conduct shall be evidence of such knowledge, approval, or acquiescence.

(2) *Conduct imputed to individuals associated with participant.* The fraudulent, criminal, or other seriously improper conduct of a participant may be imputed to any officer, director, shareholder, partner, employee, or other individual associated with the participant who participated in, knew of, or had reason to know of the participant's conduct.

(3) *Conduct of one participant imputed to other participants in a joint venture.* The fraudulent, criminal, or other seriously improper conduct of one participant in a joint venture, grant pursuant to a joint application, or similar arrangement may be imputed to other participants if the conduct occurred for or on behalf of the joint venture, grant pursuant to a joint application, or similar arrangement may be imputed to other participants if the conduct occurred for or on behalf of the joint venture, grant pursuant to a joint application, or similar arrangement or with the knowledge, approval, or acquiescence of these participants. Acceptance of the benefits derived from the conduct shall be evidence of such knowledge, approval, or acquiescence.

Subpart D—Suspension

§ 76.400 General.

(a) The suspending official may suspend a person for any of the causes in § 76.405 using procedures established in §§ 76.410 through 76.413.

(b) Suspension is a serious action to be imposed only when:

(1) There exists adequate evidence of one or more of the causes set out in § 76.405, and

(2) Immediate action is necessary to protect the public interest.

(c) In assessing the adequacy of the evidence, the agency should consider how much information is available, how credible it is given the circumstances, whether or not important allegations are corroborated, and what inferences can reasonably be drawn as a result. This assessment should include an examination of basic documents such as grants, cooperative agreements, loan authorizations, and contracts.

§ 76.405 Causes for suspension.

(a) Suspension may be imposed in accordance with the provisions of §§ 76.400 through 76.413 upon adequate evidence:

(1) To suspect the commission of an offense listed in § 76.305(a); or

(2) That a cause for debarment under § 76.305 may exist.

(b) Indictment shall constitute adequate evidence for purposes of suspension actions.

§ 76.410 Procedures.

(a) *Investigation and referral.* Information concerning the existence of a cause for suspension from any source shall be promptly reported, investigated, and referred, when appropriate, to the suspending official for consideration. After consideration, the suspending official may issue a notice of suspension.

(b) *Decisionmaking process.* HHS shall process suspension actions as informally as practicable, consistent with principles of fundamental fairness, using the procedures in § 76.411 through § 76.413.

§ 76.411 Notice of suspension.

When a respondent is suspended, notice shall immediately be given:

(a) That suspension has been imposed;

(b) That the suspension is based on an indictment, conviction, or other adequate evidence that the respondent has committed irregularities seriously reflecting on the propriety of further Federal Government dealings with the respondent;

(c) Describing any such irregularities in terms sufficient to put the respondent on notice without disclosing the Federal Government's evidence;

(d) Of the cause(s) relied upon under § 76.405 for imposing suspension;

(e) That the suspension is for a temporary period pending the completion of an investigation or ensuing legal, debarment, or Program Fraud Civil Remedies Act proceedings;

(f) Of the provisions of § 76.411 through § 76.413 and any other HHS procedures, if applicable, governing suspension decisionmaking; and

(g) Of the effect of the suspension.

§ 76.412 Opportunity to contest suspension.

(a) *Submission in opposition.* Within 30 days after receipt of the notice of suspension, the respondent may submit, in person, in writing, or through a representative, information and argument in opposition to the suspension.

(b) *Additional proceedings as to disputed material facts.*

(1) If the suspending official finds that the respondent's submission in opposition raises a genuine dispute over facts material to the suspension, respondent(s) shall be afforded an opportunity to appear with a representative, submit documentary evidence, present witnesses, and confront any witness the agency presents, unless:

(i) The action is based on an indictment, conviction or civil judgment, or

(ii) A determination is made, on the basis of Department of Justice advice, that the substantial interests of the Federal Government in pending or contemplated legal proceedings based on the same facts as the suspension would be prejudiced.

(2) A transcribed record of any additional proceedings shall be prepared and made available at cost to the respondent, upon request, unless the respondent and the agency, by mutual agreement, waive the requirement for a transcript.

§ 76.413 Suspending official's decision.

The suspending official may modify or terminate the suspension (for example, see § 76.320(c) for reasons for reducing the period or scope of debarment) or may leave it in force. However, a decision to modify or terminate the suspension shall be without prejudice to the subsequent imposition of suspension by any other agency or debarment by any agency. The decision shall be rendered in accordance with the following provisions:

(a) *No additional proceedings necessary.* In actions: based on an indictment, conviction, or civil judgment; in which there is no genuine dispute over material facts; or in which additional proceedings to determine disputed material facts have been denied on the basis of Department of Justice advice, the suspending official shall make a decision on the basis of all the information in the administrative record, including any submission made by the respondent. The decision shall be made within 45 days after receipt of any information and argument submitted by the respondent, unless the suspending official extends this period for good cause.

(b) *Additional proceedings necessary*

(1) In actions in which additional proceedings are necessary to determine disputed material facts, written findings of fact shall be prepared. The suspending official shall base the decision on the facts as found, together with any information and argument submitted by the respondent and any other information in the administrative record.

(2) The suspending official may refer matters involving disputed material facts to another official for findings of fact. The suspending official may reject any such findings, in whole or in part, only after specifically determining them to be arbitrary or capricious or clearly erroneous.

(c) *Notice of suspending official's decision.* Prompt written notice of the suspending official's decision shall be sent to the respondent.

§ 76.415 Period of suspension.

(a) Suspension shall be for a temporary period pending the completion of an investigation or ensuing legal, debarment, or Program Fraud Civil Remedies Act proceedings, unless terminated sooner by the suspending official or as provided in paragraph (b) of this section.

(b) If legal or administrative proceedings are not initiated within 12 months after the date of the suspension notice, the suspension shall be terminated unless an Assistant Attorney General or United States Attorney requests its extension in writing, in which case it may be extended for an additional six months. In no event may a suspension extend beyond 18 months, unless such proceedings have been initiated within that period.

(c) The suspending official shall notify the Department of Justice of an impending termination of a suspension, at least 30 days before the 12-month period expires, to give that Department an opportunity to request an extension.

§ 76.420 Scope of suspension.

The scope of a suspension is the same as the scope of a debarment (see § 76.325), except that the procedures of §§ 76.410 through 76.413 shall be used in imposing a suspension.

Subpart E—Responsibilities of GSA, Agency and Participants

§ 76.500 GSA responsibilities.

(a) In accordance with the OMB guidelines, GSA shall compile, maintain, and distribute a list of all persons who have been debarred, suspended, or voluntarily excluded by agencies under Executive Order 12549 and these regulations, and those who have been determined to be ineligible.

(b) At a minimum, this list shall indicate:

(1) The names and addresses of all debarred, suspended, ineligible, and voluntarily excluded persons, in alphabetical order, with cross-references when more than one name is involved in a single action;

(2) The type of action;

(3) The cause for the action;

(4) The scope of the action;

(5) Any termination date for each listing; and

(6) The agency and name and telephone number of the agency point of contact for the action.

§ 76.505 HHS responsibilities.

(a) The agency shall provide GSA with current information concerning debarments, suspension, determinations of ineligibility, and voluntary exclusions it has taken. Until February 18, 1989, the agency shall also provide GSA and OMB with information concerning all transactions in which HHS has granted exceptions under § 76.215 permitting participation by debarred, suspended, or voluntarily excluded persons.

(b) Unless an alternative schedule is agreed to by GSA, the agency shall advise GSA of the information set forth in § 76.500(b) and of the exceptions granted under § 76.215 within five working days after taking such actions.

(c) The agency shall direct inquiries concerning listed persons to the agency that took the action.

(d) HHS officials shall check the Nonprocurement List before entering covered transactions to determine whether a participant in a primary transaction is debarred, suspended, ineligible, or voluntarily excluded (Tel. #).

(e) Agency officials shall check the Nonprocurement List before approving principals or lower tier participants where agency approval of the principal or lower tier participant is required under the terms of the transaction, to determine whether such principals or participants are debarred, suspended, ineligible, or voluntarily excluded.

§ 76.510 Participants' responsibilities.

(a) *Certification by participants in primary covered transactions.* Each participant shall submit the certification in Appendix A to this Part for it and its principals at the time the participant submits its proposal in connection with a primary covered transaction, except that States need only complete such certification as to their principals. Participants may decide the method and frequency by which they determine the eligibility of their principals. In addition, each participant may, but is not required to, check the Nonprocurement List for its principals (Tel. #). Adverse information on the certification will not necessarily result in denial of participation. However, the certification, and any additional information pertaining to the certification submitted by the participant, shall be considered in the administration of covered transactions.

(b) *Certification by participants in lower tier covered transactions.* (1) Each participant shall require participants in lower tier covered transactions to include the certification in Appendix B to this Part for it and its principals in any proposal submitted in connection with such lower tier covered transactions.

(2) A participant may rely upon the certification of a prospective participant in a lower tier covered transaction that it and its principals are not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction by any Federal agency, unless it knows that the certification is erroneous. Participants may decide the method and frequency by which they determine the eligiblity of their principals. In addition, a participant may, but is not required to, check the Nonprocurement List for its principals and for participants (Tel. #).

(c) *Changed circumstances regarding certification.* A participant shall provide immediate written notice to HHS if at any time the participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances. Participants in lower tier covered transactions shall provide the same updated notice to the participant to which it submitted its proposals.

Subpart F—Drug-Free Workplace Requirements (Grants)

SOURCE: 55 FR 21688, 21702, May 25, 1990, unless otherwise noted.

§ 76.600 Purpose.

(a) The purpose of this subpart is to carry out the Drug-Free Workplace Act of 1988 by requiring that—

(1) A grantee, other than an individual, shall certify to the agency that it will provide a drug-free workplace;

(2) A grantee who is an individual shall certify to the agency that, as a condition of the grant, he or she will not engage in the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance in conducting any activity with the grant.

(b) Requirements implementing the Drug-Free Workplace Act of 1988 for contractors with the agency are found at 48 CFR subparts 9.4, 23.5, and 52.2.

§ 76.605 Definitions.

(a) Except as amended in this section, the definitions of § 76.105 apply to this subpart.

(b) For purposes of this subpart—

(1) *Controlled substance* means a controlled substance in schedules I through V of the Controlled Substances Act (21 U.S.C. 812), and as further defined by regulation at 21 CFR 1308.11 through 1308.15;

(2) *Conviction* means a finding of guilt (including a plea of nolo contendere) or imposition of sentence, or both, by any judicial body charged with the responsibility to determine violations of the Federal or State criminal drug statutes;

(3) *Criminal drug statute* means a Federal or non-Federal criminal statute involving the manufacture, distribution, dispensing, use, or possession of any controlled substance;

(4) *Drug-free workplace* means a site for the performance of work done in connection with a specific grant at which employees of the grantee are prohibited from engaging in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance;

(5) *Employee* means the employee of a grantee directly engaged in the performance of work under the grant, including:

(i) All *direct charge* employees;

(ii) All *indirect charge* employees, unless their impact or involvement is insignificant to the performance of the grant; and,

(iii) Temporary personnel and consultants who are directly engaged in the performance of work under the grant and who are on the grantee's payroll.

This definition does not include workers not on the payroll of the grantee (e.g., volunteers, even if used to meet a matching requirement; consultants or independent contractors not on the payroll; or employees of subrecipients or subcontractors in covered workplaces);

(6) *Federal agency* or *agency* means any United States executive department, military department, government corporation, government controlled corporation, any other establishment in the executive branch (including the Executive Office of the President), or any independent regulatory agency;

(7) *Grant* means an award of financial assistance, including a cooperative agreement, in the form of money, or property in lieu of money, by a Federal agency directly to a grantee. The term grant includes block grant and entitlement grant programs, whether or not exempted from coverage under the grants management governmentwide common rule on uniform administrative requirements for grants and cooperative agreements. The term does not include technical assistance that provides services instead of money, or other assistance in the form of loans, loan guarantees, interest subsidies, insurance, or direct appropriations; or any veterans' benefits to individuals, i.e., any benefit to veterans, their families, or survivors by virtue of the service of a veteran in the Armed Forces of the United States;

(8) *Grantee* means a person who applies for or receives a grant directly from a Federal agency (except another Federal agency);

(9) *Individual* means a natural person;

(10) *State* means any of the States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, or any agency of a State, exclusive of institutions of higher education, hospitals, and units of local government. A State instrumentality will be considered part of the State government if it has a written determination from a State government that such State considers the instrumentality to be an agency of the State government.

§ 76.610 Coverage.

(a) This subpart applies to any grantee of the agency.

(b) This subpart applies to any grant, except where application of this subpart would be inconsistent with the international obligations of the United States or the laws or regulations of a foreign government. A determination of such inconsistency may be made only by the agency head or his/her designee.

(c) The provisions of subparts A, B, C, D and E of this part apply to matters covered by this subpart, except where specifically modified by this subpart. In the event of any conflict between provisions of this subpart and other provisions of this part, the provisions of this subpart are deemed to control with respect to the implementation of drug-free workplace requirements concerning grants.

§ 76.615 Grounds for suspension of payments, suspension or termination of grants, or suspension or debarment.

A grantee shall be deemed in violation of the requirements of this subpart if the agency head or his or her official designee determines, in writing, that—

(a) The grantee has made a false certification under § 76.630;

(b) With respect to a grantee other than an individual—

(1) The grantee has violated the certification by failing to carry out the requirements of paragraphs (A)(a)-(g) and/or (B) of the certification (Alternate I to Appendix C) or

(2) Such a number of employees of the grantee have been convicted of

violations of criminal drug statutes for violations occurring in the workplace as to indicate that the grantee has failed to make a good faith effort to provide a drug-free workplace.

(c) With respect to a grantee who is an individual—

(1) The grantee has violated the certification by failing to carry out its requirements (Alternate II to Appendix C); or

(2) The grantee is convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity.

§ 76.620 Effect of violation.

(a) In the event of a violation of this subpart as provided in § 76.615, and in accordance with applicable law, the grantee shall be subject to one or more of the following actions:

(1) Suspension of payments under the grant;

(2) Suspension or termination of the grant; and

(3) Suspension or debarment of the grantee under the provisions of this part.

(b) Upon issuance of any final decision under this part requiring debarment of a grantee, the debarred grantee shall be ineligible for award of any grant from any Federal agency for a period specified in the decision, not to exceed five years (*see* § 76.320(a)(2) of this part).

§ 76.625 Exception provision.

The agency head may waive with respect to a particular grant, in writing, a suspension of payments under a grant, suspension or termination of a grant, or suspension or debarment of a grantee if the agency head determines that such a waiver would be in the public interest. This exception authority cannot be delegated to any other official.

§ 76.630 Certification requirements and procedures.

(a)(1) As a prior condition of being awarded a grant, each grantee shall make the appropriate certification to the Federal agency providing the grant, as provided in Appendix C to this part.

(2) Grantees are not required to make a certification in order to continue receiving funds under a grant awarded before March 18, 1989, or under a no-cost time extension of such a grant. However, the grantee shall make a one-time drug-free workplace certification for a non-automatic continuation of such a grant made on or after March 18, 1989.

(b) Except as provided in this section, all grantees shall make the required certification for each grant. For mandatory formula grants and entitlements that have no application process, grantees shall submit a one-time certification in order to continue receiving awards.

(c) A grantee that is a State may elect to make one certification in each Federal fiscal year. States that previously submitted an annual certification are not required to make a certification for Fiscal Year 1990 until June 30, 1990. Except as provided in paragraph (d) of this section, this certification shall cover all grants to all State agencies from any Federal agency. The State shall retain the original of this statewide certification in its Governor's office and, prior to grant award, shall ensure that a copy is submitted individually with respect to each grant, unless the Federal agency has designated a central location for submission.

(d)(1) The Governor of a State may exclude certain State agencies from the statewide certification and authorize these agencies to submit their own certifications to Federal agencies. The statewide certification shall name any State agencies so excluded.

(2) A State agency to which the statewide certification does not apply, or a State agency in a State that does not have a statewide certification, may elect to make one certification in each Federal fiscal year. State agencies that previously submitted a State agency certification are not required to make a certification for Fiscal Year 1990 until June 30, 1990. The State agency shall retain the original of this State agency-wide certification in its central office and, prior to grant award, shall ensure that a copy is submitted individually with respect to each grant,

unless the Federal agency designates a central location for submission.

(3) When the work of a grant is done by more than one State agency, the certification of the State agency directly receiving the grant shall be deemed to certify compliance for all workplaces, including those located in other State agencies.

(e)(1) For a grant of less than 30 days performance duration, grantees shall have this policy statement and program in place as soon as possible, but in any case by a date prior to the date on which performance is expected to be completed.

(2) For a grant of 30 days or more performance duration, grantees shall have this policy statement and program in place within 30 days after award.

(3) Where extraordinary circumstances warrant for a specific grant, the grant officer may determine a different date on which the policy statement and program shall be in place.

§ 76.635 Reporting of and employee sanctions for convictions of criminal drug offenses.

(a) When a grantee other than an individual is notified that an employee has been convicted for a violation of a criminal drug statute occurring in the workplace, it shall take the following actions:

(1) Within 10 calendar days of receiving notice of the conviction, the grantee shall provide written notice, including the convicted employee's position title, to every grant officer, or other designee on whose grant activity the convicted employee was working, unless a Federal agency has designated a central point for the receipt of such notifications. Notification shall include the identification number(s) for each of the Federal agency's affected grants.

(2) Within 30 calendar days of receiving notice of the conviction, the grantee shall do the following with respect to the employee who was convicted.

(i) Take appropriate personnel action against the employee, up to and including termination, consistent with requirements of the Rehabilitation Act of 1973, as amended; or

(ii) Require the employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency.

(b) A grantee who is an individual who is convicted for a violation of a criminal drug statute occurring during the conduct of any grant activity shall report the conviction, in writing, within 10 calendar days, to his or her Federal agency grant officer, or other designee, unless the Federal agency has designated a central point for the receipt of such notices. Notification shall include the identification number(s) for each of the Federal agency's affected grants.

(Approved by the Office of Management and Budget under control number 0001-0002)

[55 FR 21688, 21702, May 25, 1990]

APPENDIX A TO PART 76—CERTIFICATION REGARDING DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS—PRIMARY COVERED TRANSACTIONS

Instructions for Certification

1. By signing and submitting this proposal, the prospective primary participant is providing the certification set out below.

2. The inability of a person to provide the certification required below will not necessarily result in denial of participation in this covered transaction. The prospective participant shall submit an explanation of why it cannot provide the certification set out below. The certification or explanation will be considered in connection with the department or agency's determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.

3. The certification in this clause is a material representation of fact upon which reliance was placed when the department or agency determined to enter into this transaction. If it is later determined that the prospective primary participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause of default.

4. The prospective primary participant shall privide immediate written notice to

the department or agency to whom this proposal is submitted if at any time the prospective primary participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

5. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of the rules implementing Executive Order 12549. You may contact the department or agency to which this proposal is being submitted for assistance in obtaining a copy of those regulations.

6. The prospective primary participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency entering into this transaction.

7. The prospective primary participant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transaction," provided by the department or agency entering into this covered transaction, without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

8. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List (Tel. #).

9. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

10. Except for transactions authorized under paragraph 6 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

Certification Regarding Debarment, Suspension, and Other Responsibility Matters—Primary Covered Transactions

(1) The prospective primary participant certifies to the best of its knowledge and belief, that it and its principals:

(a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;

(b) Have not within a three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(c) Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

(d) Have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State or local) terminated for cause or default.

(2) Where the prospective primary participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

APPENDIX B TO PART 76—CERTIFICATION REGARDING DEBARMENT, SUSPENSION, INELIGIBILTY AND VOLUNTARY EXCLUSION—LOWER TIER COVERED TRANSACTIONS

Instructions for Certification

1. By signing and submitting this proposal, the prospective lower tier participant is providing the certification set out below.

2. The certification in this clause is a material representation of fact upon which reliance was placed when this transaction was entered into. If it is later determined that the prospective lower tier participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originat-

ed may pursue available remedies, including suspension and/or debarment.

3. The prospective lower tier participant shall provide immediate written notice to the person to which this proposal is submitted if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

4. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. You may contact the person to which this proposal is submitted for assistance in obtaining a copy of those regulations.

5. The prospective lower tier participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from in this covered transaction, unless authorized by the department or agency with which this transaction originated.

6. The prospective lower tier participant further agrees by submitting this proposal that it will include this clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transaction," without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

7. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List (Tel. #).

8. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

9. Except for transactions authorized under paragraph 5 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transactions

(1) The prospective lower tier participant certifies, by submission of this proposal, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.

(2) Where the prospective lower tier participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

APPENDIX C TO PART 76—CERTIFICATION REGARDING DRUG-FREE WORKPLACE REQUIREMENTS

Instructions for Certification

1. By signing and/or submitting this application or grant agreement, the grantee is providing the certification set out below.

2. The certification set out below is a material representation of fact upon which reliance is placed when the agency awards the grant. If it is later determined that the grantee knowingly rendered a false certification, or otherwise violates the requirements of the Drug-Free Workplace Act, the agency, in addition to any other remedies available to the Federal Government, may take action authorized under the Drug-Free Workplace Act.

3. For grantees other than individuals, Alternate I applies.

4. For grantees who are individuals, Alternate II applies.

5. Workplaces under grants, for grantees other than individuals, need not be identified on the certification. If known, they may be identified in the grant application. If the grantee does not identify the workplaces at the time of application, or upon award, if there is no application, the grantee must keep the identity of the workplace(s) on file in its office and make the information available for Federal inspection. Failure to identify all known workplaces constitutes a violation of the grantee's drug-free workplace requirements.

6. Workplace identifications must include the actual address of buildings (or parts of buildings) or other sites where work under the grant takes place. Categorical descrip-

tions may be used (e.g., all vehicles of a mass transit authority or State highway department while in operation, State employees in each local unemployment office, performers in concert halls or radio studios).

7. If the workplace identified to the agency changes during the performance of the grant, the grantee shall inform the agency of the change(s), if it previously identified the workplaces in question (see paragraph five).

8. Definitions of terms in the Nonprocurement Suspension and Debarment common rule and Drug-Free Workplace common rule apply to this certification. Grantees' attention is called, in particular, to the following definitions from these rules:

Controlled substance means a controlled substance in Schedules I through V of the Controlled Substances Act (21 U.S.C. 812) and as further defined by regulation (21 CFR 1308.11 through 1308.15);

Conviction means a finding of guilt (including a plea of nolo contendere) or imposition of sentence, or both, by any judicial body charged with the responsibility to determine violations of the Federal or State criminal drug statutes;

Criminal drug statute means a Federal or non-Federal criminal statute involving the manufacture, distribution, dispensing, use, or possession of any controlled substance;

Employee means the employee of a grantee directly engaged in the performance of work under a grant, including: (i) All *direct charge* employees; (ii) All *indirect charge* employees unless their impact or involvement is insignificant to the performance of the grant; and, (iii) Temporary personnel and consultants who are directly engaged in the performance of work under the grant and who are on the grantee's payroll. This definition does not include workers not on the payroll of the grantee (e.g., volunteers, even if used to meet a matching requirement; consultants or independent contractors not on the grantee's payroll; or employees of subrecipients or subcontractors in covered workplaces).

Certification Regarding Drug-Free Workplace Requirements

Alternate I. (Grantees Other Than Individuals)

A. The grantee certifies that it will or will continue to provide a drug-free workplace by:

(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(b) Establishing an ongoing drug-free awareness program to inform employees about—

(1) The dangers of drug abuse in the workplace;

(2) The grantee's policy of maintaining a drug-free workplace;

(3) Any available drug counseling, rehabilitation, and employee assistance programs; and

(4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will—

(1) Abide by the terms of the statement; and

(2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;

(e) Notifying the agency in writing, within ten calendar days after receiving notice under paragraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer or other designee on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;

(f) Taking one of the following actions, within 30 calendar days of receiving notice under paragraph (d)(2), with respect to any employee who is so convicted—

(1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

(2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

B. The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant:

Place of Performance (Street address, city, county, state, zip code)

Check ☐ if there are workplaces on file that are not identified here.

Alternate II. (Grantees Who Are Individuals)

(a) The grantee certifies that, as a condition of the grant, he or she will not engage in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance in conducting any activity with the grant;

(b) If convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity, he or she will report the conviction, in writing, within 10 calendar days of the conviction, to every grant officer or other designee, unless the Federal agency designates a central point for the receipt of such notices. When notice is made to such a central point, it shall include the identification number(s) of each affected grant.

[55 FR 21690, 21702, May 25, 1990]

PART 77—REMEDIAL ACTIONS APPLICABLE TO LETTER OF CREDIT ADMINISTRATION

Sec.

77.1 Purpose.
77.2 Scope.
77.3 Conditions that may give rise to remedial actions.
77.4 Remedial actions.
77.5 Remedial action procedures.
77.6 Emergency procedures.

Authority: 5 U.S.C. 301.

Source: 50 FR 781, Jan. 7, 1985, unless otherwise noted.

§ 77.1 Purpose.

Letters of credit with the United States Treasury, issued by the Department to States or other grantees and contractors, are a convenient means for disbursing Federal funds to recipients of grant awards or contracts (recipient organizations) under the programs of this and other Executive Departments. The sound and efficient operation of the letter-of-credit system is dependent in large part upon the honesty, good faith, and responsible financial management of recipient organizations that receive funds pursuant to letters of credit. This part sets forth conditions that may prompt the Department to seek remedial action against a recipient organization operating under a letter of credit and the procedures that will be used to reach a final decision regarding the taking of remedial actions against a recipient organization.

§ 77.2 Scope.

The regulations in this part apply to all recipient organizations under any program administered by the Department through which the organization receives Federal funds under a letter of credit.

§ 77.3 Conditions that may give rise to remedial actions.

If the Department determines that any of the following conditions is present in a recipient organization's administration of a letter of credit, it may take remedial actions against the organization:

(a) A recipient organization draws Federal funds through its letter of credit in excess of the aggregate grant award or contract authority currently available to it.

(b) A recipient organization draws Federal funds for a particular program in excess of currently available grant award or contract authority for that program, even though the organization may not have exceeded its aggregate grant award or contract authority.

(c) A recipient organization fails to file timely all reports and other data required by the Department in connection with its grant awards, contracts, or letter of credit.

(d) A recipient organization accumulates, through its letter of credit or otherwise, excess amounts of Federal funds relative to its actual and immediate disbursement requirements.

(e) A recipient organization's cash management system fails to comply with generally accepted accounting principles or Departmental regulations or demonstrates irregularities, misrepresentations, fraud, or abuse in its operation.

§ 77.4 Remedial actions.

If, after the conclusion of the procedures set forth in § 77.5 or § 77.6 the

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Department finds that one or more of the conditions set forth in § 77.3 is or has been present, the Department may take the following remedial actions against a recipient organization's use of its letter of credit:

(a) The Department may place special limits, restrictions, or controls upon the recipient organization's use of its letter of credit.

(b) The Department may require more frequent or more detailed financial reporting from the recipient organization.

(c) The Department may suspend, reduce, or terminate the recipient organization's use of its letter of credit.

§ 77.5 Remedial action procedures.

Except as provided in § 77.6, the Department will use the following procedures whenever it seeks the remedial action specified in § 77.4.

(a) *Notice.* Prior to taking remedial action, the Department will provide the recipient organization written notice of its intended action setting forth both the legal and factual reasons therefor. Notice may be provided by certified or express mail, TWX, telegram, delivery, or similar means.

(b) *Opportunity to respond.* (1) The recipient organization has 30 days after receipt of the notice in which to submit to the Department a written statement setting forth any legal and factual reasons why it believes the proposed remedial action would be inappropriate. If no response is received by the Department within the 30-day period, the Department may make the proposed remedial action effective immediately. If a response opposing the taking of remedial action is received from the recipient organization within the 30-day period, no remedial action will be taken until a final decision has been reached under paragraph (c) of this section. (2) The Department may prepare a written reply to the recipient organization's response. Any such reply will be forwarded to the deciding official together with the notice sent to the recipient organization and the organization's response, and a copy of the reply will be served on the recipient organization.

(c) *Departmental decision.* The Department's decision to take remedial action under this part will be made by an official of the Department who had no involvement with the initial determination to seek remedial action. The deciding official may affirm, reverse, or modify the initial determination. In making the decision, the official will consider only the notice provided by the Department, the recipient organization's statement, the Department's reply, together with any other documents attached to them, and statements at any informal conference held pursuant to paragraph (d) of this section. The official's decision will be provided to the recipient organization in writing and will constitute the Department's final administrative action on the matter.

(d) *Informal conference.* If, in the judgment of the official designated to make a final decision, it would materially enhance his ability to resolve the matters in dispute, he may convene an informal conference to question or hear an oral presentation by the parties. If an informal conference is convened it will be transcribed.

(e) *Effect of decision.* The decision in a proceeding under this section affects only the recipient organization's obligations related to its letter of credit and does not determine the organization's ultimate liability with respect to improperly spent funds or other misconduct.

§ 77.6 Emergency procedures.

(a) Should the Department determine that it cannot adequately protect assets of the Federal government available to a recipient organization under its letter of credit without taking remedial action prior to the procedures specified in § 77.5, it may immediately take remedial action subject to the subsequent completion of those procedures.

(b) Where the Department has taken remedial action as described in paragraph (a) of this section, it will notify the , recipient organization orally of the remedial action within one business day of its imposition and in writing within seven business days of its imposition. The written notice will conform to that described in § 77.5(a).

(c) After receipt of the written notice, the recipient organization will have the same opportunity to respond as described in § 77.5(b)(1).

(d) The Department will issue a final decision in writing no later than twenty days following receipt of any response submitted by the recipient organization.

PART 79—PROGRAM FRAUD CIVIL REMEDIES

Sec.
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Authority: Secs. 6101-6104, Pub. L. 99-509, 100 Stat. 1874 (31 U.S.C. 3801-3812).

Source: 53 FR 11659, Apr. 8, 1988, unless otherwise noted.

§ 79.1 Basis and purpose.

(a) *Basis.* This part implements the Program Fraud Civil Remedies Act of 1986, Pub. L. 99-509, §§ 6101-6104, 100 Stat. 1874 (October 21, 1986), to be codified at 31 U.S.C. 3801-3812. 31 U.S.C. 3809 of the statute requires each authority head to promulgate regulations necessary to implement the provisions of the statute.

(b) *Purpose.* This part (1) establishes administrative procedures for imposing civil penalties and assessments against persons who make, submit, or present, or cause to be made, submitted, or presented, false, fictitious, or fraudulent claims or written statements to authorities or to their agents, and (2) specifies the hearing and appeal rights of persons subject to allegations of liability for such penalties and assessments.

§ 79.2 Definitions.

ALJ means an Administrative Law Judge in the authority appointed pursuant to 5 U.S.C. 3105 or detailed to the authority pursuant to 5 U.S.C. 3344.

Authority means the Department of Health and Human Services.

Authority head means the Departmental Grant Appeals Board of the Department of Health and Human Services.

Benefit means, in the context of "statement," anything of value, including but not limited to any advantage, preference, privilege, license, permit, favorable decision, ruling, status, or loan guarantee.

Claim means any request, demand, or submission—

(a) Made to the authority for property, services, or money (including money representing grants, loans, insurance, or benefits);

(b) Made to a recipient of property, services, or money from the authority or to a party to a contract with the authority—

(1) For property or services if the United States—

(i) Provided such property or services;

(ii) Provided any portion of the funds for the purchase of such property or services; or

(iii) Will reimburse such recipient or party for the purchase of such property or services; or

(2) For the payment of money (including money representing grants, loans, insurance, or benefits) if the United States—

(i) Provided any portion of the money requested or demanded; or

(ii) Will reimburse such recipient or party for any portion of the money paid on such request or demand: or

(c) Made to the authority which has the effect of decreasing an obligation to pay or account for property, services, or money.

Complaint means the administrative complaint served by the reviewing official on the defendant under § 79.7.

Defendant means any person alleged in a complaint under § 79.7 to be liable for a civil penalty or assessment under § 79.3.

Department means the Department of Health and Human Services.

Government means the United States Government.

Individual means a natural person.

Initial decision means the written decision of the ALJ required by §§ 79.10 or 79.37, and includes a revised initial decision issued following a remand or a motion for reconsideration.

Investigating official means the Inspector General of the Department of Health and Human Services or an officer or employee of the Office of the Inspector General designated by the Inspector General and serving in a position for which the rate of basic pay is not less than the minimum rate of basic pay for grade GS-16 under the General Schedule.

Knows or has reason to know, means that a person, with respect to a claim or statement—

(a) Has actual knowledge that the claim or statement is false, fictitious, or fraudulent;

(b) Acts in deliberate ignorance of the truth or falsity of the claim or statement; or

(c) Acts in reckless disregard of the truth or falsity of the claim or statement.

Makes, wherever it appears, shall include the terms presents, submits, and causes to be made, presented, or submitted. As the context requires, *making* or *made,* shall likewise include the corresponding forms of such terms.

Person means any individual, partnership, corporation, association or private organization, and includes the plural of that term.

Representative means an attorney who is a member in good standing of the bar of any State, Territory, or possession of the United States or of the District of Columbia or the Commonwealth of Puerto Rico.

Reviewing official means the General Counsel of the Department or his or her designee who is—

(a) Not subject to supervision by, or required to report to, the investigating official;

(b) Not employed in the organizational unit of the authority in which the investigating official is employed; and

(c) Serving in a position for which the rate of basic pay is not less than the minimum rate of basic pay for grade GS-16 under the General Schedule.

Statement means any representation, certification, affirmation, document, record, or accounting or bookkeeping entry made—

(a) With respect to a claim or to obtain the approval or payment of a claim (including relating to eligibility to make a claim); or

(b) With respect to (including relating to eligibility for)—

(1) A contract with, or a bid or proposal for a contract with; or

(2) A grant, loan, or benefit from, the authority, or any State, political subdivision of a State, or other party,

if the United States Government provides any portion of the money or property under such contract or for such grant, loan, or benefit, or if the Government will reimburse such State, political subdivision, or party for any portion of the money or property under such contract or for such grant, loan, or benefit,

§ 79.3 Basis for civil penalties and assessments.

(a) *Claims.* (1) Except as provided in paragraph (c) of this section, any person who makes a claim that the person knows or has reason to know—

(i) Is false, fictitious, or fraudulent;

(ii) Includes, or is supported by, any written statement which asserts a material fact which is false, fictitious, or fraudulent;

(iii) Includes, or is supported by, any written statement that—

(A) Omits a material fact;

(B) Is false, fictitious, or fraudulent as a result of such omission; and

(C) Is a statement in which the person making such statement has a duty to include such material fact; or

(iv) Is for payment for the provision of property or services which the person has not provided as claimed, shall be subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than $5,000 for each such claim.

(2) Each voucher, invoice, claim form, or other individual request or demand for property, services, or money constitutes a separate claim.

(3) A claim shall be considered made to the authority, recipient, or party when such claim is actually made to an agent, fiscal intermediary, or other entity, including any State or political subdivision thereof, acting for or on behalf of the authority, recipient, or party.

(4) Each claim for property, services, or money is subject to a civil penalty regardless of whether such property, services, or money is actually delivered or paid.

(5) If the Government has made any payment (including transferred property or provided services) on a claim, a person subject to a civil penalty under paragraph (a)(1) of this section shall also be subject to an assessment of not more than twice the amount of such claim or that portion thereof that is determined to be in violation of paragraph (a)(1). Such assessment shall be in lieu of damages sustained by the Government because of such claim.

(b) *Statements.* (1) Except as provided in paragraph (c) of this section, any person who makes a written statement that—

(i) The person knows or has reason to know—

(A) Asserts a material fact which is false, fictitious, or fraudulent; or

(B) Is false, fictitious, or fraudulent because it omits a material fact that the person making the statement has a duty to include in such statement; and

(ii) Contains, or is accompanied by, an express certification or affirmation of the truthfulness and accuracy of the contents of the statement,

shall be subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than $5,000 fo reach such statement.

(2) Each representation, certification, or affirmation constitutes a separate statement.

(3) A statement shall be considered made to the authority when such statement is actually made to an agent, fiscal intermediary, or other entity, including any State or political subdivision thereof, acting for or on behalf of the authority.

(c) *Applications for certain benefits.* (1) In the case of any claim or statement made by any individual relating to any of the benefits listed in paragraph (c)(2) of this section received by such individual, such individual may be held liable for penalties and assessments under this section only if such claim or statement is made by such individual in making application for such benefits with respect to such individual's eligibility to receive such benefits.

(2) For purposes of paragraph (c) of this section, the term "benefits" means—

(i) Benefits under the supplemental security income program under title XVI of the Social Security Act;

(ii) Old age, survivors, and disability insurance benefits under title II of the Social Security Act;

(iii) Benefits under title XVIII of the Social Security Act;

(iv) Aid to families with dependent children under a State plan approved under section 402(a) of the Social Security Act;

(v) Medical assistance under a State plan approved under section 1902(a) of the Social Security Act;

(vi) Benefits under title XX of the Social Security Act;

(vii) Benefits under section 336 of the Older Americans Act; or,

(viii) Benefits under the Low-Income Home Energy Assistance Act of 1981, which are intended for the personal use of the individual who receives the benefits or for a member of the individual's family.

(d) No proof of specific intent to defraud is required to establish liability under this section.

(e) In any case in which it is determined that more than one person is liable for making a claim or statement under this section, each such person may be held liable for a civil penalty.

(f) In any case in which it is determined that more than one person is liable for making a claim under this section on which the Government has made payment (including transferred property or provided services), an assessment may be imposed against any such person or jointly and severally against any combination of such persons.

§ 79.4 Investigation.

(a) If an investigating official concludes that a subpoena pursuant to the authority conferred by 31 U.S.C. 3804(a) is warranted—

(1) The subpoena so issued shall notify the person to whom it is addressed of the authority under which the subpoena is issued and shall identify the records or documents sought;

(2) The investigating official may designate a person to act on his or her behalf to receive the documents sought; and

(3) The person receiving such subpoena shall be required to tender to the investigating official, or the person designated to receive the documents, a certification that—

(i) The documents sought have been produced;

(ii) Such documents are not available and the reasons therefor; or

(iii) Such documents suitably identified, have been withheld based upon the assertion of an identified privilege.

(b) If the investigating official concludes that an action under the Program Fraud Civil Remedies Act may be warranted, the investigating official shall submit a report containing the findings and conclusions of such investigation to the reviewing official.

(c) Nothing in this section shall preclude or limit an investigating official's discretion to refer allegations directly to the Department of Justice for suit under the False Claims Act or other civil relief, or to defer or postpone a report or referral to the reviewing official to avoid interference with a criminal investigation or prosecution.

(d) Nothing in this section modifies any responsibility of an investigating official to report violations of criminal law to the Attorney General.

§ 79.5 Review by the reviewing official.

(a) If, based on the report of the investigating official under § 79.4(b), the reviewing official determines that there is adequate evidence to believe that a person is liable under § 79.3, the reviewing official shall transmit to the Attorney General a written notice of the reviewing official's attention to issue a complaint under § 79.7.

(b) Such notice shall include—

(1) A statement of the reviewing official's reasons for issuing a complaint;

(2) A statement specifying the evidence that supports the allegations of liability;

(3) A description of the claims or statements upon which the allegations of liability are based;

(4) An estimate of the amount of money, or the value of property, services, or other benefits, requested or demanded in violation of § 79.3 of this part;

(5) A statement of any exculpatory or mitigating circumstances that may relate to the claims or statements known by the reviewing official or the investigating official; and

(6) A statement that there is a reasonable prospect of collecting an ap-

propriate amount of penalties and assessments.

§ 79.6 Prerequisites for issuing a complaint.

(a) The reviewing official may issue a complaint under § 79.7 only if—

(1) The Department of Justice approves the issuance of a complaint in a written statement described in 31 U.S.C. 3803(b)(1), and

(2) In the case of allegations of liability under § 79.3(a) with respect to a claim, the reviewing official determines that, with respect to such claim or a group of related claims submitted at the same time such claim is submitted (as defined in paragraph (b) of this section), the amount of money, or the value of property or services, demanded or requested in violation of § 79.3(a) does not exceed $150,000.

(b) For the purposes of this section, a related group of claims submitted at the same time shall include only those claims arising from the same transaction (e.g., grant, loan, application, or contract) that are submitted simultaneously as part of a single request, demand, or submission.

(c) Nothing in this section shall be construed to limit the reviewing official's authority to join in a single complaint against a person claims that are unrelated or were not submitted simultaneously, regardless of the amount of money, or the value of property or services, demanded or requested.

§ 79.7 Complaint.

(a) On or after the date the Department of Justice approves the issuance of a complaint in accordance with 31 U.S.C. 3803(b)(1), the reviewing official may serve a complaint on the defendant, as provided in § 79.8.

(b) The complaint shall state—

(1) The allegations of liability against the defendant, including the statutory basis for liability, an identification of the claims or statements that are the basis for the alleged liability, and the reasons why liability allegedly arises from such claims or statements;

(2) The maximum amount of penalties and assessments for which the defendant may be held liable;

(3) Instructions for filing an answer to request a hearing, including a specific statement of the defendant's right to request a hearing by filing an answer and to be represented by a representative; and

(4) That failure to file an answer as set forth in § 79.9 will result in the imposition of the maximum amount of penalties and assessments without right to appeal, as provided in § 79.10.

(c) At the same time the reviewing official serves the complaint, he or she shall serve the defendant with a copy of these regulations.

§ 79.8 Service of complaint.

(a) Service of a complaint must be made by certified or registered mail or by delivery in any manner authorized by Rule 4(d) of the Federal Rules of Civil Procedure. Service is complete upon receipt.

(b) Proof of service, stating the name and address of the person on whom the complaint was served, and the manner and date of service, may be made by—

(1) Affidavit of the individual serving the complaint by delivery;

(2) A United States Postal Service return receipt card acknowledging receipt; or

(3) Written acknowledgment of receipt by the defendant or his or her representative.

§ 79.9 Answer.

(a) The defendant may request a hearing by filing an answer with the reviewing official within 30 days of service of the complaint. An answer shall be deemed to be a request for hearing.

(b) In the answer, the defendant—

(1) Shall admit or deny each of the allegations of liability made in the complaint;

(2) Shall state any defense on which the defendant intends to rely;

(3) May state any reasons why the defendant contends that the penalties and assessments should be less than the statutory maximum; and

(4) Shall state the name, address, and telephone number of the person authorized by the defendant to act as defendant's representative, if any.

(c) If the defendant is unable to file an answer meeting the requirements of paragraph (b) of this section within the time provided, the defendant, before that time expires, may file with the reviewing official a general answer denying liability and requesting a hearing, and a request for an extension of time within which to file an answer meeting the requirements of paragraph (b) of this section. As provided in § 79.11, the reviewing official shall file promptly with the ALJ the complaint, the general answer denying liability, and the request for an extension of time. For good cause shown, the ALJ may grant the defendant up to 30 additional days within which to file an answer meeting the requirements of paragraph (b) of this section.

§ 79.10 Default upon failure to file an answer.

(a) If the defendant does not file an answer within the time prescribed in § 79.9(a), the reviewing official may refer the complaint to the ALJ.

(b) Upon the referral of the complaint, the ALJ shall promptly serve on the defendant in the manner prescribed in § 79.8, a notice that an initial decision will be issued under this section.

(c) The ALJ shall assume the facts alleged in the complaint to be true and, if such facts establish liability under § 79.3, the ALJ shall issue an initial decision imposing the maximum amount of penalties and assessments allowed under the statute.

(d) Except as otherwise provided in this section, by failing to file a timely answer, the defendant waives any right to further review of the penalties and assessments imposed under paragraph (c) of this section, and the initial decision shall become final and binding upon the parties 30 days after it is issued.

(e) If, before such an initial decision becomes final, the defendant files a motion with the ALJ seeking to reopen on the grounds that extraordinary circumstances prevented the defendant from filing an answer, the initial decision shall be stayed pending the ALJ's decision on the motion.

(f) If, on such motion, the defendant can demonstrate extraordinary circumstances excusing the failure to file a timely answer, the ALJ shall withdraw the initial decision in paragraph (c) of this section, if such a decision has been issued, and shall grant the defendant an opportunity to answer the complaint.

(g) A decision of the ALJ denying a defendant's motion under paragraph (e) of this section is not subject to reconsideration under § 79.38.

(h) The defendant may appeal to the authority head the decision denying a motion to reopen by filing a notice of appeal with the authority head within 15 days after the ALJ denies the motion. The timely filing of a notice of appeal shall stay the initial decision until the authority head decides the issue.

(i) If the defendant files a timely notice of appeal with the authority head, the ALJ shall forward the record of the proceeding to the authority head.

(j) The authority head shall decide expeditiously whether extraordinary circumstances excuse the defendant's failure to file a timely answer based solely on the record before the ALJ.

(k) If the authority head decides that extraordinary circumstances excuse the defendant's failure to file a timely answer, the authority head shall remand the case to the ALJ with instructions to grant the defendant an opportunity to answer.

(l) If the authority head decides that the defendant's failure to file a timely answer is not excused, the authority head shall reinstate the initial decision of the ALJ, which shall become final and binding upon the parties 30 days after the authority head issues such decision.

§ 79.11 Referral of complaint and answer to the ALJ.

Upon receipt of an answer, the reviewing official shall file the complaint and answer with the ALJ.

§ 79.12 Notice of hearing.

(a) When the ALJ receives the complaint and answer, the ALJ shall promptly serve a notice of hearing upon the defendant in the manner prescribed by § 79.8. At the same time, the ALJ shall send a copy of such notice to the representative for the Government.

(b) Such notice shall include—

(1) The tentative time and place, and the nature of the hearing;

(2) The legal authority and jurisdiction under which the hearing is to be held;

(3) The matters of fact and law to be asserted;

(4) A description of the procedures for the conduct of the hearing;

(5) The name, address, and telephone number of the representative of the Government and of the defendant, if any; and

(6) Such other matters as the ALJ deems appropriate.

§ 79.13 Parties to the hearing.

(a) The parities to the hearing shall be the defendant and the authority.

(b) Pursuant to 31 U.S.C. 3730(c)(5), a private plaintiff under the False Claims Act may participate in these proceedings to the extent authorized by the provisions of that Act.

§ 79.14 Separation of functions.

(a) The investigating official, the reviewing official, and any employee or agent of the authority who takes part in investigating, preparing, or presenting a particular case may not, in such case or a factually related case—

(1) Participate in the hearing as the ALJ;

(2) Participate or advise in the initial decision or the review of the initial decision by the authority head, except as a witness or a representative in public proceedings; or

(3) Make the collection of penalties and assessments under 31 U.S.C. 3806.

(b) The ALJ shall not be responsible to, or subject to the supervision or direction of, the investigating official or the reviewing official.

(c) Except as provided in paragraph (a) of this section, the representative for the Government may be employed anywhere in the authority, including in the offices of either the investigating official or the reviewing official.

§ 79.15 Ex parte contacts.

No party or person (except employees of the ALJ's office) shall communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 79.16 Disqualification of reviewing official or ALJ.

(a) A reviewing official or ALJ in a particular case may disqualify himself or herself at any time.

(b) A party may file with the ALJ a motion for disqualification of a reviewing official or an ALJ. Such motion shall be accompanied by an affidavit alleging personal bias or other reason for disqualification.

(c) Such motion and affidavit shall be filed promptly upon the party's discovery of reasons requiring disqualification, or such objections shall be deemed waived.

(d) Such affidavit shall state specific facts that support the party's belief that personal bias or other reason for disqualification exists and the time and circumstances of the party's discovery of such facts. It shall be accompanied by a certificate of the representative of record that it is made in good faith.

(e) Upon the filing of such a motion and affidavit, the ALJ shall proceed no further in the case until he or she resolves the matter of disqualification in accordance with paragraph (f) of this section.

(f)(1) If the ALJ determines that a reviewing official is disqualified, the ALJ shall dismiss the complaint without prejudice.

(2) If the ALJ disqualifies himself or herself, the case shall be reassigned promptly to another ALJ.

(3) If the ALJ denies a motion to disqualify, the authority head may determine the matter only as part of his or her review of the initial decision upon appeal, if any.

§ 79.17 Rights of parties.

Except as otherwise limited by this part, all parties may—

(a) Be accompanied, represented, and advised by a representative;

(b) Participate in any conference held by the ALJ;

(c) Conduct discovery;

(d) Agree to stipulations of fact or law, which shall be made part of the record;

(e) Present evidence relevant to the issues at the hearing;

(f) Present and cross-examine witnesses;

(g) Present oral arguments at the hearing as permitted by the ALJ; and

(h) Submit written briefs and proposed findings of fact and conclusions of law after the hearing.

§ 79.18 Authority of the ALJ.

(a) The ALJ shall conduct a fair and impartial hearing, avoid delay, maintain order, and assure that a record of the proceeding is made.

(b) The ALJ has the authority to—

(1) Set and change the date, time, and place of the hearing upon reasonable notice to the parties;

(2) Continue or recess the hearing in whole or in part for a reasonable period of time;

(3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Issue subpoenas requiring the attendance of witnesses and the production of documents at depositions or at hearings;

(6) Rule on motions and other procedural matters;

(7) Regulate the scope and timing of discovery;

(8) Regulate the course of the hearing and the conduct of representatives and parties;

(9) Examine witnesses;

(10) Receive, rule on, exclude, or limit evidence;

(11) Upon motion of a party, take official notice of facts;

(12) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact;

(13) Conduct any conference, argument, or hearing on motions in person or by telephone; and

(14) Exercise such other authority as is necessary to carry out the responsibilities of the ALJ under this part.

(c) The ALJ does not have the authority to find Federal statutes or regulations invalid.

§ 79.19 Prehearing conferences.

(a) The ALJ may schedule prehearing conferences as appropriate.

(b) Upon the motion of any party, the ALJ shall schedule at least one prehearing conference at a reasonable time in advance of the hearing.

(c) The ALJ may use prehearing conferences to discuss the following:

(1) Simplication of the issues;

(2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;

(3) Stipulations and admissions of fact——, or as to the contents and authenticity of documents;

(4) Whether the parties can agree to submission of the case on a stipulated record;

(5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of other parties) and written argument;

(6) Limitation of the number of witnesses;

(7) Scheduling dates for the exchange of witness lists and of proposed exhibits;

(8) Discovery;

(9) The time and place for the hearing; and

(10) Such other matters as may tend to expedite the fair and just disposition of the proceedings.

(d) The ALJ may issue an order containing all matters agreed upon by the parties or ordered by the ALJ at a prehearing conference.

§ 79.20 Disclosure of documents.

(a) Upon written request to the reviewing official, the defendant may review any relevant and material documents, transcripts, records, and other materials that relate to the allegations set out in the complaint and upon which the findings and conclusions of the investigating official under § 79.4(b) are based, unless such documents are subject to a privilege under Federal law. Upon payment of fees for duplication, the defendant may obtain copies of such documents.

(b) Upon written request to the reviewing official, the defendant also may obtain a copy of all exculpatory information in the possession of the reviewing official or investigating official relating to the allegations in the complaint, even if it is contained in a document that would otherwise be privileged. If the document would otherwise be privileged, only that portion containing exculpatory information must be disclosed.

(c) The notice sent to the Attorney General from the reviewing official as described in § 79.5 is not discoverable under any circumstances.

(d) The defendant may file a motion to compel disclosure of the documents subject to the provisions of this section. Such a motion may only be filed with the ALJ following the filing of an answer pursuant to § 79.9.

§ 79.21 Discovery.

(a) The following types of discovery are authorized:

(1) Requests for production of documents for inspection and copying;

(2) Requests for admission of the contents or authenticity of any relevant document or of the truth of any revelant fact;

(3) Written interrogatories; and

(4) Depositions.

(b) For the purpose of this section and §§ 79.22 and 79.23, the term "documents" includes information, documents, reports, answers, records, accounts, papers, and other data and documentary evidence. Nothing contained herein shall be interpreted to require the creation of a document.

(c) Unless mutually agreed to by the parties, discovery is available only as ordered by the ALJ. The ALJ shall regulate the timing of discovery.

(d) *Motions for discovery.* (1) A party seeking discovery may file a motion with the ALJ. Such a motion shall be accompanied by a copy of the requested discovery, or in the case of depositions, a summary of the scope of the proposed deposition.

(2) Within ten days of service, a party may file an opposition to the motion and/or a motion for protective order as provided in § 79.24.

(3) The ALJ may grant a motion for discovery only if he or she finds that the discovery sought—

(i) Is necessary for the expeditious, fair, and reasonable consideration of the issues;

(ii) Is not unduly costly or burdensome;

(iii) Will not unduly delay the proceeding; and

(iv) Does not seek privileged information.

(4) The burden of showing that discovery should be allowed is on the party seeking discovery.

(5) The ALJ may grant discovery subject to a protective order under § 79.24.

(e) *Depositions.* (1) If a motion for deposition is granted, the ALJ shall issue a subpoena for the deponent, which may require the deponent to produce documents. The subpoena shall specify the time and place at which the deposition will be held.

(2) The party seeking to depose shall serve the subpoena in the manner prescribed in § 79.8.

(3) The deponent may file with the ALJ a motion to quash the subpoena or a motion for a protective order within ten days of service.

(4) The party seeking to depose shall provide for the taking of a verbatim transcript of the deposition, which it shall make available to all other parties for inspection and copying.

(f) Each party shall bear its own costs of discovery.

§ 79.22 Exchange of witness lists, statements and exhibits.

(a) At least 15 days before the hearing or at such other time as may be ordered by the ALJ, the parties shall exchange witness lists, copies of prior statements of proposed witnesses, and copies of proposed hearing exhibits, including copies of any written statements that the party intends to offer in lieu of live testimony in accordance with § 79.33(b). At the time the above documents are exchanged, any party that intends to rely on the transcript of deposition testimony in lieu of live testimony at the hearing, if permitted by the ALJ, shall provide each party with a copy of the specific pages of the transcript it intends to introduce into evidence.

(b) If a party objects, the ALJ shall not admit into evidence the testimony of any witness whose name does not appear on the witness list or any exhibit not provided to the opposing party as provided above unless the ALJ finds good cause for the failure or that there is no prejudice to the objecting party.

(c) Unless another party objects within the time set by the ALJ, documents exchanged in accordance with paragraph (a) of this section shall be deemed to be authentic for the purpose of admissibility at the hearing.

§ 79.23 Subpoenas for attendance at hearing.

(a) A party wishing to procure the appearance and testimony of any individual at the hearing may request that the ALJ issue a subpoena.

(b) A subpoena requiring the attendance and testimony of an individual may also require the individual to produce documents at the hearing.

(c) A party seeking a subpoena shall file a written request therefor not less than 15 days before the date fixed for the hearing unless otherwise allowed by the ALJ for good cause shown. Such request shall specify any documents to be produced and shall designate the witnesses and describe the address and location thereof with sufficient particularity to permit such witnesses to be found.

(d) The subpoena shall specify the time and place at which the wintess is to appear and any documents the witness is to produce.

(e) The party seeking the subpoena shall serve it in the manner prescribed in § 79.8, except that a subpoena on a party or upon an individual under the control of a party may be served as prescribed in § 79.26(b).

(f) A party or the individual to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within ten days after service or on or before the time specified in the subpoena for compliance if it is less than ten days after service.

§ 79.24 Protective order.

(a) A party or a prospective witness or deponent may file a motion for a protective order with respect to discovery sought by an opposing party or with repect to the hearing, seeking to limit the availability or disclosure of evidence.

(b) In issuing a protective order, the ALJ may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the following:

(1) That the discovery not be had;

(2) That the discovery may be had only on specified terms and conditions, including a designation of the time or place;

(3) That the discovery may be had only through a method of discovery other than that requested:

(4) That certain matters not be inquired into, or that the scope of discovery be limited to certain matters;

(5) That discovery be conducted with no one present except persons designated by the ALJ;

(6) That the contents of discovery or evidence be sealed;

(7) That a deposition after being sealed be opened only by order of the ALJ;

(8) That a trade secret or other confidential research, development, commercial information, or facts pertaining to any criminal investigation, proceeding, or other administrative investigation not be disclosed or be disclosed only in a designated way; or

(9) That the parties simultaneously file specified documents or information enclosed in sealed envelopes to be opened as directed by the ALJ.

§ 79.25 Fees.

The party requesting a subpoena shall pay the cost of the fees and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in United States District Court. A check for witness fees and mileage shall accompany the subpoena when served, except that when a subpoena is issued on behalf of the authority, a check for witness fees and mileage need not accompany the subpoena.

§ 79.26 Form, filing and service of papers.

(a) *Form.* (1) Documents filed with the ALJ shall include an original and two copies.

(2) Every pleading and paper filed in the proceeding shall contain a caption setting forth the title of the action, the case number assigned by the ALJ, and a designation of the paper (*e.g.*, motion to quash subpoena).

(3) Every pleading and paper shall be signed by, and shall contain the address and telephone number of, the party or the person on whose behalf the paper was filed, or his or her representative.

(4) Papers are considered filed when they are mailed. Date of mailing may be established by a certificate from the party or its representative or by proof that the document was sent by certified or registered mail.

(b) *Service.* A party filing a document with the ALJ shall, at the time of filing, serve a copy of such document on every other party. Service upon any party of any document other than those required to be served as prescribed in § 79.8 shall be made by delivering a copy or by placing a copy of the document in the United States mail, postage prepaid, and addressed to the party's last known address. When a party is represented by a representative, service shall be made upon such representative in lieu of the actual party.

(c) *Proof of service.* A certificate of the individual serving the document by personal delivery or by mail, setting forth the manner of service, shall be proof of service.

§ 79.27 Computation of time.

(a) In computing any period of time under this part or in an order issued thereunder, the time begins with the day following the act, event, or default, and includes the last day of the period, unless it is a Saturday, Sunday, or legal holiday observed by the Federal government, in which event it includes the next business day.

(b) Except as provided in paragraph (c) of this section, when the period of time allowed is less than seven days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal government shall be excluded from the computation.

(c) Where a document has been served or issued by placing it in the mail, an additional five calendar days will be added to the time permitted for any response.

§ 79.28 Motions.

(a) Any application to the ALJ for an order or ruling shall be by motion. Motions shall state the relief sought, the authority relied upon, and the facts alleged, and shall be filed with the ALJ and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions shall be in writing. The ALJ may require that oral motions be reduced to writing.

(c) Within 15 days after a written motion is served, or such other time as may be fixed by the ALJ, any party may file a response to such motion.

(d) The ALJ may not grant a written motion before the time for filing responses thereto has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny such motion without awaiting a response.

(e) The ALJ shall make a reasonable effort to dispose of all outstanding motions prior to the beginning of the hearing.

§ 79.29 Sanctions.

(a) The ALJ may sanction a person, including any party or representative, for—

(1) Failing to comply with an order, rule, or procedure governing the proceeding;

(2) Failing to prosecute or defend an action; or

(3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

(b) Any such sanction, including but not limited to those listed in paragraphs (c), (d), and (e) of this section, shall reasonably relate to the severity and nature of the failure or misconduct.

(c) When a party fails to comply with an order, including an order for taking a deposition, the production of evidence within the party's control, or a request for admission, the ALJ may—

(1) Draw an inference in favor of the requesting party with regard to the information sought;

(2) In the case of requests for admission, deem each matter of which an admission is requested to be admitted;

(3) Prohibit the party failing to comply with such order from introducing evidence concerning, or otherwise relying upon, testimony relating to the information sought; and

(4) Strike any part of the pleadings or other submissions of the party failing to comply with such request.

(d) If a party fails to prosecute or defend an action under this part commenced by service of a notice of hearing, the ALJ may dismiss the action or may issue an initial decision imposing penalties and assessments.

(e) The ALJ may refuse to consider any motion, request, response, brief or other document which is not filed in a timely fashion.

§ 79.30 The hearing and burden of proof.

(a) The ALJ shall conduct a hearing on the record in order to determine whether the defendant is liable for a civil penalty or assessment under § 79.3 and, if so, the appropriate amount of any such civil penalty or assessment considering any aggravating or mitigating factors.

(b) The authority shall prove defendant's liability and any aggravating factors by a preponderance of the evidence.

(c) The defendant shall prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

(d) The hearing shall be open to the public unless otherwise ordered by the ALJ for good cause shown.

§ 79.31 Determining the amount of penalties and assessments.

(a) In determining an appropriate amount of civil penalties and assessments, the ALJ and the authority head, upon appeal, should evaluate any circumstances that mitigate or aggravate the violation and should articulate in their opinions the reasons that support the penalties and assessments they impose. Because of the intangible costs of fraud, the expense of investigating such conduct, and the need to deter others who might be similarly tempted, ordinarily double damages and a significant civil penalty should be imposed.

(b) Although not exhaustive, the following factors are among those that may influence the ALJ and the authority head in determining the amount of penalties and assessments to impose with respect to the misconduct (i.e., the false, fictitious, or fraudulent claims or statements) charged in the complaint:

(1) The number of false, fictitious, or fraudulent claims or statements;

(2) The time period over which such claims or statements were made;

(3) The degree of the defendant's culpability with respect to the misconduct;

(4) The amount of money or the value of the property, services, or benefit falsely claimed;

(5) The value of the Government's actual loss as a result of the misconduct, including foreseeable consequential damages and the costs of investigation;

(6) The relationship of the amount imposed as civil penalties to the amount of the Government's loss;

(7) The potential or actual impact of the misconduct upon national defense, public health or safety, or public confidence in the management of Government programs and operations, including particularly the impact on the intended beneficiaries of such programs;

(8) Whether the defendant has engaged in a pattern of the same or similar misconduct;

(9) Whether the defendant attempted to conceal the misconduct;

(10) The degree to which the defendant has involved others in the misconduct or in concealing it;

(11) Where the misconduct of employees or agents is imputed to the defendant, the extent to which the defendant's practices fostered or attempted to preclude such misconduct;

(12) Whether the defendant cooperated in or obstructed an investigation of the misconduct;

(13) Whether the defendant assisted in identifying and prosecuting other wrongdoers;

(14) The complexity of the program or transaction, and the degree of the defendant's sophistication with respect to it, including the extent of the defendant's prior participation in the program or in similar transactions;

(15) Whether the defendant has been found, in any criminal, civil, or administrative proceeding, to have engaged in similar misconduct or to have dealt dishonestly with the Government of the United States or of a State, directly or indirectly; and

(16) The need to deter the defendant and others from engaging in the same or similar misconduct.

(c) Nothing in this section shall be construed to limit the ALJ or the authority head from considering any other factors that in any given case may mitigate or aggravate the offense for which penalties and assessments are imposed.

§ 79.32 Location of hearing.

(a) The hearing may be held—

(1) In any judicial district of the United States in which the defendant resides or transacts business;

(2) In any judicial district of the United States in which the claim or statement in issue was made; or

(3) In such other place as may be agreed upon by the defendant and the ALJ.

(b) Each party shall have the opportunity to present argument with respect to the location of the hearing.

(c) The hearing shall be held at the place and at the time ordered by the ALJ.

§ 79.33 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing shall be given orally by witnesses under oath or affirmation.

(b) At the discretion of the ALJ, testimony may be admitted in the form of a written statement or deposition. Any such written statement must be provided to all other parties along with the last known address of such witness, in a manner which allows sufficient time for other parties to subpoena such witness for cross-examination at the hearing. Prior written statements of witnesses proposed to testify at the hearing and deposition transcripts shall be exchanged as provided in § 79.22(a).

(c) The ALJ shall exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to (1) make the interrogation and presentation effective for the ascertainment of the truth, (2) avoid needless consumption of time, and (3) protect witnesses from harassment or undue embarrassment.

(d) The ALJ shall permit the parties to conduct such cross-examination as may be required for a full and true disclosure of the facts.

(e) At the discretion of the ALJ, a witness may be cross-examined on matters relevant to the proceeding without regard to the scope of his or her direct examination. To the extent permitted by the ALJ, cross-examination on matters outside the scope of direct examination shall be conducted in the manner of direct examination and may proceed by leading questions only if the witness is a hostile witness, an adverse party, or a witness identified with an adverse party.

(f) Upon motion of any party, the ALJ shall order witnesses excluded so that they cannot hear the testimony of other witnesses. This rule does not authorize exclusion of—

(1) A party who is an individual;

(2) In the case of a party that is not an individual, an officer or employee of the party appearing for the entity pro se or designated by the party's representative; or

(3) An individual whose presence is shown by a party to be essential to the presentation of its case, including an individual employed by the Government engaged in assisting the representative for the Government.

§ 79.34 Evidence.

(a) The ALJ shall determine the admissibility of evidence.

(b) Except as provided in this part, the ALJ shall not be bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate, *e.g.*, to exclude unreliable evidence.

(c) The ALJ shall exclude irrelevant and immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence may be excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement shall be inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.

(g) The ALJ shall permit the parties to introduce rebuttal witnesses and evidence.

(h) All documents and other evidence offered or taken for the record shall be open to examination by all parties, unless otherwise ordered by the ALJ pursuant to § 79.24.

§ 79.35 The record.

(a) The hearing will be recorded and transcribed. Transcripts may be obtained following the hearing from the ALJ at a cost not to exceed the actual cost of duplication.

(b) The transcript of testimony, exhibits and other evidence admitted at the hearing, and all papers and requests filed in the proceeding constitute the record for the decision by the ALJ and the authority head.

(c) The record may be inspected and copied (upon payment of a reasonable fee) by anyone, unless otherwise ordered by the ALJ pursuant to § 79.24.

§ 79.36 Post-hearing briefs.

The ALJ may require the parties to file post-hearing briefs. In any event, any party may file a post-hearing brief. The ALJ shall fix the time for filing such briefs, not to exceed 60 days from the date the party receives the transcript of the hearing or, if applicable, the stipulated record. Such briefs may be accompanied by proposed findings of fact and conclusions of law. The ALJ may permit the parties to file reply briefs.

§ 79.37 Initial decision.

(a) The ALJ shall issue an initial decision based only on the record, which shall contain findings of fact, conclusions of law, and the amount of any penalties and assessments imposed.

(b) The findings of fact shall include a finding on each of the following issues:

(1) Whether the claims or statements identified in the complaint, or any portions thereof, violate § 79.3;

(2) If the person is liable for penalties or assessments, the appropriate amount of any such penalties or assessments considering any mitigating or aggravating factors that he or she finds in the case, such as those described in § 79.31.

(c) The ALJ shall promptly serve the initial decision on all parties within 90 days after the time for submission of post-hearing briefs and reply briefs (if permitted) has expired. The ALJ shall at the same time serve all parties with a statement describing the right of any defendant determined to be liable for a civil penalty or assessment to file a motion for reconsideration with the ALJ or a notice of appeal with the authority head. If the ALJ fails to meet the deadline contained in this paragraph, he or she shall notify the parties of the reason for the delay and shall set a new deadline.

(d) Unless the initial decision of the ALJ is timely appealed to the authority head, or a motion for reconsideration of the initial decision is timely filed, the initial decision shall constitute the final decision of the authority head and shall be final and binding on the parties 30 days after it is issued by the ALJ.

§ 79.38 Reconsideration of initial decision.

(a) Except as provided in paragraph (d) of this section, any party may file a motion for reconsideration of the initial decision within 20 days of receipt of the initial decision. If service was made by mail, receipt will be presumed to be five days from the date of mailing in the absence of contrary proof.

(b) Every such motion must set forth the matters claimed to have been erroneously decided and the nature of the alleged errors. Such motion shall be accompanied by a supporting brief.

(c) Responses to such motions shall be allowed only upon request of the ALJ.

(d) No party may file a motion for reconsideration of an initial decision that has been revised in response to a previous motion for reconsideration.

(e) The ALJ may dispose of a motion for reconsideration by denying it or by issuing a revised initial decision.

(f) If the ALJ denies a motion for reconsideration, the initial decision shall constitute the final decision of the authority head and shall be final and binding on the parties 30 days after the ALJ denies the motion, unless the initial decision is timely appealed to the authority head in accordance with § 79.39.

(g) If the ALJ issues a revised initial decision, that decision shall constitute the final decision of the authority head and shall be final and binding on the parties 30 days after it is issued, unless it is timely appealed to the authority head in accordance with § 79.39.

§ 79.39 Appeal to authority head.

(a) Any defendant who has filed a timely answer and who is determined in an initial decision to be liable for a civil penalty or assessment may appeal such decision to the authority head by filing a notice of appeal with the authority head in accordance with this section.

(b)(1) A notice of appeal may be filed at any time within 30 days after the ALJ issues an initial decision. However, if another party files a motion for reconsideration under § 79.38, consideration of the appeal shall be stayed automatically pending resolution of the motion for reconsideration.

(2) If a motion for reconsideration is timely filed, a notice of appeal must be filed within 30 days after the ALJ denies the motion or issues a revised initial decision, whichever applies.

(3) If no motion for reconsideration is timely filed, a notice of appeal must be filed within 30 days after the ALJ issues the initial decision.

(4) The authority head may extend the initial 30-day period for an additional 30-days if the defendant files with the authority head a request for an extension within the initial 30 day period and shows good cause.

(c) If the defendant files a timely notice of appeal with the authority head, and the time for filing motions for reconsideration under § 79.38 has expired, the ALJ shall forward the record of the proceeding to the authority head.

(d) A notice of appeal shall be accompanied by a written brief specifying exceptions to the initial decision and reasons supporting the exceptions.

(e) The representative for the Government may file a brief in opposition to exceptions within 30 days of receiving the notice of appeal and accompanying brief.

(f) There is no right to appear personally before the authority head.

(g) There is no right to appeal any interlocutory ruling by the ALJ.

(h) In reviewing the initial decision, the authority head shall not consider any objection that was not raised before the ALJ unless a demonstration is made of extraordinary circumstances causing the failure to raise the objection.

(i) If any party demonstrates to the satisfaction of the authority head that additional evidence not presented at such hearing is material and that there were reasonable grounds for the failure to present such evidence at such hearing, the authority head shall remand the matter to the ALJ for consideration of such additional evidence.

(j) The authority head may affirm, reduce, reverse, compromise, remand, or settle any penalty or assessment determined by the ALJ in any initial decision.

(k) The authority head shall promptly serve each party to the appeal with a copy of the decision of the authority head and a statement describing the right of any person determined to be liable for a penalty or assessment to seek judicial review.

(l) Unless a petition for review is filed as provided in 31 U.S.C. 3805 after a defendant has exhausted all administrative remedies under this part and within 60 days after the date on which the authority head serves the defendant with a copy of the authority head's decision, a determination that a defendant is liable under § 79.3 is final and is not subject to judicial review.

§ 79.40 Stays ordered by the Department of Justice.

If at any time the Attorney General or an Assistant Attorney General designated by the Attorney General transmits to the authority head a written finding that continuation of the administrative process described in this part with respect to a claim or statement may adversely affect any pending or potential criminal or civil action related to such claim or statement, the authority head shall stay the process immediately. The authority head may order the process resumed only upon receipt of the written authorization of the Attorney General.

§ 79.41 Stay pending appeal.

(a) An initial decision is stayed automatically pending disposition of a motion for reconsideration or of an appeal to the authority head.

(b) No administrative stay is available following a final decision of the authority head.

§ 79.42 Judicial review.

Section 3805 of title 31, United States Code, authorizes judicial review by an appropriate United States District Court of a final decision of the authority head imposing penalties or assessments under this part and specifies the procedures for such review.

§ 79.43 Collection of civil penalties and assessments.

Sections 3806 and 3808(b) of title 31, United States Code, authorize actions for collection of civil penalties and assessments imposed under this part and specify the procedures for such actions.

§ 79.44 Right to administrative offset.

The amount of any penalty or assessment which has become final, or for which a judgment has been entered under § 79.42 or § 79.43, or any amount agreed upon in a compromise or settlement under § 79.46, may be collected by administrative offset under 31 U.S.C. 3716, except that an administrative offset may not be made under this subsection against a refund of an overpayment of Federal taxes, then or later owing by the United States to the defendant.

§ 79.45 Deposit in Treasury of United States.

All amounts collected pursuant to this part shall be deposited as miscellaneous receipts in the Treasury of the United States, except as provided in 31 U.S.C. 3806(g).

§ 79.46 Compromise or settlement.

(a) Parties may make offers of compromise or settlement at any time.

(b) The reviewing official has the exclusive authority to compromise or settle a case under this part at any time after the date on which the reviewing official is permitted to issue a complaint and before the date on which the ALJ issues an initial decision.

(c) The authority head has exclusive authority to compromise or settle a case under this part at any time after the date on which the ALJ issues an initial decision, except during the pendency of any review under § 79.42 or during the pendency of any action to collect penalties and assessments under § 79.43.

(d) The Attorney General has exclusive authority to compromise or settle a case under this part during the pendency of any review under § 79.42 or of any action to recover penalties and assessments under 31 U.S.C. 3806.

(e) The investigating official may recommend settlement terms to the reviewing official, the authority head, or the Attorney General, as appropriate. The reviewing official may recommend settlement terms to the authority head, or the Attorney General, as appropriate.

(f) Any compromise or settlement must be in writing.

§ 79.47 Limitations.

(a) The notice of hearing with respect to a claim or statement must be served in the manner specified in § 79.8 within 6 years after the date on which such claim or statement is made.

(b) If the defendant fails to file a timely answer, service of a notice under § 79.10(b) shall be deemed a notice of hearing for purposes of this section.

(c) The statute of limitations may be extended by agreement of the parties.

PART 80—NONDISCRIMINATION UNDER PROGRAMS RECEIVING FEDERAL ASSISTANCE THROUGH THE DEPARTMENT OF HEALTH AND HUMAN SERVICES EFFECTUATION OF TITLE VI OF THE CIVIL RIGHTS ACT OF 1964

Sec.
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Appendix A to Part 80—Federal Financial Assistance to Which These Regulations Apply

Appendix B to Part 80—Guidelines for Eliminating Discrimination and Denial of Services on the Basis of Race, Color, National Origin, Sex, and Handicap in Vocational Education Programs

Authority: Sec. 602, 78 Stat. 252; 42 U.S.C. 2000d-1.

§ 80.1 Purpose.

The purpose of this part is to effectuate the provisions of title VI of the Civil Rights Act of 1964 (hereafter referred to as the "Act") to the end that no person in the United States shall; on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program or activity receiving Federal financial assistance from the Department of Health and Human Services.

(Sec. 601, Civil Rights Act of 1964, 78 Stat. 252 (42 U.S.C. 2000d)

[29 FR 16298, Dec. 4, 1964, as amended at FR 17982, July 5, 1973]

§ 80.2 Application of this regulation.

This regulation applies to any program for which Federal financial assistance is authorized to be extended to a recipient under a law administered by the Department, including the Federal assisted programs and activities listed in Appendix A to this part. It applies to money paid, property transferred, or other Federal financial assistance extended after the effective date of the regulation pursuant to an application approved prior to such effective date. This regulation does not apply to (a) any Federal financial assistance by way of insurance or guaranty contracts, (b) money paid, property transferred, or other assistance extended before the effective date of this regulation, (c) the use of any assistance by any individual who is the ultimate beneficiary under any such program, or (d) any employment practice, under any such program, or any employer, employment agency, or labor organization, except to the extent described in § 80.3. The fact that a type of Federal assistance is not listed in Appendix A to this part shall not mean, if Title VI of the Act is otherwise applicable, that a program is not covered. Federal financial assistance under statutes now in force or hereinafter enacted may be added to this list by notice published in the Federal Register.

(Secs. 602, 604, Civil Rights Act of 1964, 78 Stat. 252, 253 (42 U.S.C. 2000d-1, 2000d-3)

[38 FR 17979, July 5, 1973]

§ 80.3 Discrimination prohibited.

(a) *General.* No person in the United States shall, on the ground of race, color, or national origin be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program to which this part applies.

(b) *Specific discriminatory actions prohibited.* (1) A recipient under any program to which this part applies may not, directly or through contractual or other arrangements, on ground of race, color, or national origin:

(i) Deny an individual any service, financial aid, or other benefit provided under the program;

(ii) Provide any service, financial aid, or other benefit to an individual which is different, or is provided in a different manner, from that provided to others under the program;

(iii) Subject an individual to segregation or separate treatment in any matter related to his receipt of any service, financial aid, or other benefit under the program;

(iv) Restrict an individual in any way in the enjoyment of any advantage or privilege enjoyed by others receiving any service, financial aid, or other benefit under the program;

(v) Treat an individual differently from others in determining whether he satisfies any admission, enrollment, quota, eligibility, membership or other requirement or condition which individuals must meet in order to be provided any service, financial aid, or other benefit provided under the program;

(vi) Deny an individual an opportunity to participate in the program through the provision of services or otherwise or afford him an opportunity to do so which is different from that afforded others under the program (including the opportunity to participate in the program as an employee but only to the extent set forth in paragraph (c) of this section).

(vii) Deny a person the opportunity to participate as a member of a planning or advisory body which is an integral part of the program.

(2) A recipient, in determining the types of services, financial aid, or other benefits, or facilities which will be provided under any such program, or the class of individuals to whom, or the situations in which, such services, financial aid, other benefits, or facilities will be provided under any such program, or the class of individuals to be afforded an opportunity to participate in any such program, may not, directly or through contractual or other arrangements, utilize criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program as respect individuals of a particular race, color, or national origin.

(3) In determining the site or location of a facilities, an applicant or recipient may not make selections with the effect of excluding individuals from, denying them the benefits of, or subjecting them to discrimination under any programs to which this regulation applies, on the ground of race, color, or national origin; or with the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the Act or this regulation.

(4) As used in this section, the services, financial aid, or other benefits provided under a program receiving Federal financial assistance shall be deemed to include any service, financial aid, or other benefits provided in or through a facility provided with the aid of Federal financial assistance.

(5) The enumeration of specific forms of prohibited discrimination in this paragraph and paragraph (c) of this section does not limit the generality of the prohibition in paragraph (a) of this section.

(6)(i) In administering a program regarding which the recipient has previously discriminated against persons on the ground of race, color, or national origin, the recipient must take affirmative action to overcome the effects of prior discrimination.

(ii) Even in the absence of such prior discrimination, a recipient in administering a program may take affirmative action to overcome the effects of conditions which resulted in limiting participation by persons of a particular race, color, or national origin.

(c) *Employment practices.* (1) Where a primary objective of the Federal financial assistance to a program to which this regulation applies is to provide employment, a recipient may not (directly or through contractual or other arrangements) subject an individual to discrimination on the ground of race, color, or national origin in its employment practices under such program (including recruitment or recruitment advertising, employment, layoff or termination, upgrading, demotion, or transfer, rates of pay or other forms of compensation, and use of facilities), including programs where a primary objective of the Federal financial assistance is (i) to reduce the employment of such individuals or to help them through employment to meet subsistence needs, (ii) to assist such individuals through employment to meet expenses incident to the commencement or continuation of their education or training, (iii) to provide work experience which contributes to the education or training of such individuals, or (iv) to provide remunerative activity to such individuals who because of handicaps cannot be readily absorbed in the competive labor market. The following, under existing laws, have one of the above objectives as a primary objective:

(*a*) Projects under the Public Works Acceleration Act, Pub. L. 87-658, 42 U.S.C. 2641-2643.

(*b*) Work-study under the Vocational Education Act of 1963, as amended, 20 U.S.C. 1371-1374.

(*c*) Programs assisted under laws listed in Appendix A to this part as respects employment opportunities provided thereunder, or in facilities provided thereunder, which are limited, or for which preference is given, to students, fellows, or other persons in training for the same or related employments.

(*d*) Assistance to rehabilitation facilities under the Vocational Rehabilitation Act, 29 U.S.C. 32-34, 41a and 41b.

(2) The requirements applicable to construction employment under any such program shall be those specified in or pursuant to Part III of Executive Order 11246 or any Executive order which supersedes it.

(3) Where a primary objective of the Federal financial assistance is not to provide employment, but discrimination on the ground of race, color, or national origin in the employment practices of the recipient or other persons subject to the regulation tends, on the ground of race, color, or national origin, to exclude individuals from participation in, to deny them the benefits of, or to subject them to discrimination under any program to which this regulation applies, the foregoing provisions of this paragraph (c) shall apply to the employment practices of the recipient or other persons subject to the regulation, to the extent necessary to assure equality of opportunity to, and nondiscriminatory treatment of, beneficiaries.

(d) *Indian Health and Cuban Refugee Services.* An individual shall not be deemed subjected to discrimination by reason of his exclusion from the benefits of a program limited by Federal law to individuals of a particular race, color, or national origin different from his.

(e) *Medical emergencies.* Notwithstanding the foregoing provisions of this section, a recipient of Federal financial assistance shall not be deemed to have failed to comply with paragraph (a) of this section if immediate provision of a service or other benefit to an individual is necessary to prevent his death or serious impairment of his health, and such service or other benefit cannot be provided except by or through a medical institution which refuses or fails to comply with paragraph (a) of this section.

(Secs. 601, 602, 604, Civil Rights Act of 1964, 78 Stat. 252, 253 (42 U.S.C. 2000d, 2000d-1, 2000d-3))

[29 FR 16298, Dec. 4, 1964, as amended at 38 FR 17979, 17982, July 5, 1973]

§ 80.4 Assurances required.

(a) *General.* (1) Every application for Federal financial assistance to carry out a program to which this part applies, except a program to which paragraph (b) of this section applies, and every application for Federal financial assistance to provide a facility shall, as a condition to its approval and the extension of any Federal financial assistance pursuant to the application, contain or be accompanied by an assurance that the program will be conducted or the facility operated in compliance with all requirements imposed by or pursuant to this part. In the case of an application for Federal financial assistance to provide real property or structures thereon, the assurance shall obligate the recipient, or, in the case of a subsequent transfer, the transferee, for the period during which the real property or structures are used for a purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits. In the case of personal property the assurance shall obligate the recipient for the period during which he retains ownership or possession of the property. In all other cases the assurance shall obligate the recipient for the period during which Federal financial assistance is extended pursuant to the application. The responsible Department official shall specify the form of the foregoing assurances for each program, and the extent to which like assurances will be required of subgrantees, contractors and subcontractors, transferees, successors in interest, and other participants in the program. Any such assurance shall include provisions which give the United States a right to seek its judicial enforcement.

(2) Where Federal financial assistance is provided in the form of a transfer of real property or interest therein from the Federal Government the instrument effecting or recording the transfer shall contain a covenant running with the land to assure nondiscrimination for the period during which the real property is used for a purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits. Where no transfer of property is involved but property is improved with Federal financial assistance, the recipient shall agree to include such a covenant to any subsequent transfer of the property. Where the property is obtained from the Federal Government, such covenant may also include a condition coupled with a right to be reserved by the Department to revert title to the property in the event of a breach of the covenant where, in the discretion of the responsible Department official, such a condition and right of reverter is appropriate to the statute under which the real property is obtained and to the nature of the grant and the grantee. In the event a transferee of real property proposes to mortgage or otherwise encumber the real property as security for financing construction of new, or improvement of existing, facilities on such property for the purposes for which the property was transferred, the responsible Department official may agree, upon request of the transferee and if necessary to accomplish such financing, and upon such conditions as he deems appropriate, to forbear the exercise of such right to revert title for so long as the lien of such mortgage or other encumbrance remains effective.

(b) *Continuing State programs.* Every application by a State or a State agency to carry out a program involving continuing Federal financial assistance to which this regulation applies (including the Federal financial assistance listed in Part 2 of Appendix A to this part) shall as a condition to its approval and the extension of any Federal financial assistance pursuant to the application (1) contain or be accompanied by a statement that the program is (or, in the case of a new program, will be) conducted in compliance with all requirements imposed by or pursuant to this regulation, and (2) provide or be accompanied by provision for such methods of administration for the program as are found by the responsible Department official to give reasonable assurance that the applicant and all recipients of Federal financial assistance under such program will comply with all requirements imposed by or pursuant to this regulation.

(c) *Elementary and secondary schools.* The requirements of paragraph (a) or (b) of this section with respect to any elementary or secondary school or school system shall be deemed to be satisfied if such school or school system (1) is subject to a final order of a court of the United States for the desegregation of such school or school system, and provides an assurance that it will comply with such order, including any future modification of such order, or (2) submits a plan for the desegregation of such school or school system which the responsible Department official determines is adequate to accomplish the purposes of the Act and this part, at the earliest practicable time, and provides reasonable assurance that it will carry out such plan; in any case of continuing Federal financial assistance the responsible Department official may reserve the right to redetermine, after such period as may be specified by him, the adequacy of the plan to accomplish the purposes of the Act and the regulations in this part. In any case in which a final order of a court of the United States for the desegregation of such school or school system is entered after submission of such a plan, such plan shall be revised to conform to such final order, including any future modification of such order.

(d) *Assurance from institutions.* (1) In the case of any application for Federal financial assistance to an institution of higher education (including assistance for construction, for research, for special training project, for student loans or for any other purpose), the assurance required by this section shall extend to admission practices and to all other practices relating to the treatment of students.

(2) The assurance required with respect to an institution of higher education, hospital, or any other institution, insofar as the assurance relates to the institution's practices with respect to admission or other treatment of individuals as students, patients, or clients of the institution or to the opportunity to participate in the provision of services or other benefits to such individuals, shall be applicable to the entire institution unless the applicant establishes, to the satisfaction of the responsible Department official, that the institution's practices in designated parts or programs of the institution will in no way affect its practices in the program of the institution for which Federal financial assistance is sought, or the beneficiaries of or participants in such program. If in any such case the assistance sought is for the construction of a facility or part of a facility, the assurance shall in any event extend to the entire facility and to facilities operated in connection therewith.

(Secs. 601, 602, Civil Rights Act of 1964, 78 Stat. 252 (42 U.S.C. 2000d, 2000d-1); sec. 182, 80 Stat. 1209 (42 U.S.C. 2000d-5))

[29 FR 16298, Dec. 4, 1964, as amended at 32 FR 14555, Oct. 19, 1967; 38 FR 17980, 17982, July 5, 1973]

§ 80.5 Illustrative application.

The following examples will illustrate the programs aided by Federal financial assistance of the Department. (In all cases the discrimination prohibited is discrimination on the ground of race, color, or national origin prohibited by Title VI of the Act and this regulation, as a condition of the receipt of Federal financial assistance).

(a) In federally assisted programs for the provision of health or welfare services, discrimination in the selection or eligibility of individuals to receive the services, and segregation or other discriminatory practices in the manner of providing them, are prohibited. This prohibition extends to all facilities and services provided by the grantee under the program or, if the grantee is a State, by a political subdivision of the State. It extends also to services purchased or otherwise obtained by the grantee (or political subdivision) from hospitals, nursing homes, schools, and similar institutions for beneficiaries of the program, and to the facilities in which such services are provided, subject, however, to the provisions of § 80.3(e).

(b) In federally-affected area assistance (Pub. L. 815 and Pub. L. 874) for construction aid and for general support of the operation of elementary or secondary schools, or in more limited support to such schools such as for the acquisition of equipment, the provision of vocational education, or the provision of guidance and counseling services, discrimination by the recipient school district in any of its elementary or secondary schools in the admission of students, or in the treatment of its students in any aspect of the educational process, is prohibited. In this and the following illustrations the prohibition of discrimination in the treatment of students or other trainees includes the prohibition of discrimination among the students or trainees in the availability or use of any academic, dormitory, eating, recreational, or other facilities of the grantee or other recipient.

(c) In a research, training, demonstration, or other grant to a university for activities to be conducted in a graduate school, discrimination in the admission and treatment of students in the graduate school is prohibited, and the prohibition extends to the entire university unless it satisfies the responsible Department official that practices with respect to other parts or programs of the university will not interfere, directly or indirectly, with fulfillment of the assurance required with respect to the graduate school.

(d) In a training grant to a hospital or other nonacademic institution, discrimination is prohibited in the selection of individuals to be trained and in their treatment by the grantee during their training. In a research or demonstration grant to such an institution discrimination is prohibited with respect to any educational activity and any provision of medical or other services and any financial aid to individuals incident to the program.

(e) In grants to assist in the construction of facilities for the provision of health, educational or welfare services, assurances will be required that services will be provided without discrimination, to the same extent that discrimination would be prohibited as a condition of Federal operating grants for the support of such services. Thus, as a condition of grants for the construction of academic, research, or other facilities at institutions of higher education, assurances will be required that there will be no discrimination in the admission or treatment of students. In case of hospital construction grants the assurance will apply to patients, to interns, residents, student nurses, and other trainees, and to the privilege of physicians, dentists, and other professionally qualified persons to practice in the hospital, and will apply to the entire facility for which, or for a part of which, the grant is made, and to facilities operated in connection therewith. In other construction grants the assurances required will similarly be adapted to the nature of the activities to be conducted in the facilities for construction of which the grants have been authorized by Congress.

(f) Upon transfers of real or personal surplus property for health or educational uses, discrimination is prohibited to the same extent as in the case of grants for the construction of facilities or the provision of equipment for like purposes.

(g) Each applicant for a grant for the construction of educational television facilities is required to provide an assurance that it will, in its broadcast services, give due consideration to the interests of all significant racial or ethnic groups within the population to be served by the applicant.

(h) A recipient may not take action that is calculated to bring about indirectly what this regulation forbids it to accomplish directly. Thus, a State, in selecting or approving projects or sites for the construction of public libraries which will receive Federal financial assistance, may not base its selections or approvals on criteria which have the effect of defeating or of substantially impairing accomplishments of the objectives of the Federal assistance as respects individuals of a particular race, color or national origin.

(i) In some situations, even though past discriminatory practices attributable to a recipient or applicant have been abandoned, the consequences of such practices continue to impede the full availability of a benefit. If the efforts required of the applicant or recipient under § 80.6(d), to provide information as to the availability of the program or activity and the rights of beneficiaries under this regulation, have failed to overcome these consequences, it will become necessary under the requirement stated in (i) of § 80.3(b) (6) for such applicant or recipient to take additional steps to make the benefits fully available to racial and nationality groups previously subject to discrimination. This action might take the form, for example, of special arrangements for obtaining referrals or making selections which will insure that groups previously subjected to discrimination are adequately served.

(j) Even though an applicant or recipient has never used discriminatory policies, the services and benefits of the program or activity it administers may not in fact be equally available to some racial or nationality groups. In such circumstances, an applicant or recipient may properly give special consideration to race, color, or national origin to make the benefits of its program more widely available to such groups, not then being adequately served. For example, where a university is not adequately serving members of a particular racial or nationality group, it may establish special recruitment policies to make its program better known and more readily available to such group, and take other steps to provide that group with more adequate service.

(Secs. 601, 602, Civil Rights Act of 1964, 78 Stat. 252 (42 U.S.C. 2000d, 2000d-1))

[29 FR 16298, Dec. 4, 1964; 29 FR 16988, Dec. 11, 1964, as amended at 38 FR 17980, 17982, July 5, 1973]

§ 80.6 Compliance information.

(a) *Cooperation and assistance.* The responsible Department official shall to the fullest extent practicable seek the cooperation of recipients in obtaining compliance with this part and shall provide assistance and guidance to recipients to help them comply voluntarily with this part.

(b) *Compliance reports.* Each recipient shall keep such records and submit to the responsible Department official or his designee timely, complete and accurate compliance reports at such times, and in such form and containing such information, as the responsible Department official or his designee may determine to be necessary to enable him to ascertain whether the recipient has complied or is complying with this part. For example, recipients should have available for the Department racial and ethnic data showing the extent to which members of minority groups are beneficiaries of and participants in federally-assisted programs. In the case of any program under which a primary recipient extends Federal financial assistance to any other recipient, such other recipient shall also submit such compliance reports to the primary recipient as may be necessary to enable the primary recipient to carry out its obligations under this part.

(c) *Access to sources of information.* Each recipient shall permit access by the responsible Department official or his designee during normal business hours to such of its books, records, accounts, and other sources of information, and its facilities as may be pertinent to ascertain compliance with this part. Where any information required of a recipient is in the exclusive possession of any other agency, institution or person and this agency, institution or person shall fail or refuse to furnish this information the recipient shall so certify in its report and shall set forth what efforts it has made to obtain the information. Asserted considerations of privacy or confidentiality may not operate to bar the Department from evaluating or seeking to enforce compliance with this part. Information of a confidential nature obtained in connection with compliance evaluation or enforcement shall not be disclosed except where necessary in formal enforcement proceedings or where otherwise required by law.

(d) *Information to beneficiaries and participants.* Each recipient shall make available to participants, beneficiaries, and other interested persons such information regarding the provisions of this regulation and its applicability to the program for which the recipient receives Federal financial assistance, and make such information available to them in such manner, as the responsible Department official finds necessary to apprise such persons of the protections against discrimination assured them by the Act and this regulation.

(Secs. 601, 602, Civil Rights Act of 1964, 78 Stat. 252 (42 U.S.C. 2000d, 2000d-1))

[29 FR 16298, Dec. 4, 1964, as amended at 32 FR 14555, Oct. 19, 1967; 38 FR 17981, 17982, July 5, 1973]

§ 80.7 Conduct of investigations.

(a) *Periodic compliance reviews.* The responsible Department official or his designee shall from time to time review the practices of recipients to determine whether they are complying with this part.

(b) *Complaints.* Any person who believes himself or any specific class of individuals to be subjected to discrimination prohibited by this part may by himself or by a representative file with the responsible Department official or his designee a written complaint. A complaint must be filed not later than 180 days from the date of the alleged discrimination, unless the time for filing is extended by the responsible Department official or his designee.

(c) *Investigations.* The responsible Department official or his designee will make a prompt investigation whenever a compliance review, report, complaint, or any other information indicates a possible failure to comply with this part. The investigation should include, where appropriate, a review of the pertinent practices and policies of the recipient, the circumstances under which the possible noncompliance with this part occurred, and other factors relevant to a determination as to whether the recipient has failed to comply with this part.

(d) *Resolution of matters.* (1) If an investigation pursuant to paragraph (c) of this section indicates a failure to comply with this part, the responsible Department official or his designee will so inform the recipient and the matter will be resolved by informal means whenever possible. If it has been determined that the matter cannot be resolved by informal means, action will be taken as provided for in § 80.8.

(2) If an investigation does not warrant action pursuant to paragraph (d)(1) of this section the responsible Department official or his designee will so inform the recipient and the complainant, if any, in writing.

(e) *Intimidatory or retaliatory acts prohibited.* No recipient or other person shall intimidate, threaten, coerce, or discriminate against any individual for the purpose of interfering with any right or privilege secured by section 601 of the Act or this part, or because he has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding or hearing under this part. The identity of complainants shall be kept confidential except to the extent necessary to carry out the purposes of this part, including the conduct of any investigation, hearing, or judicial proceeding arising thereunder.

(Secs. 601, 602, Civil Rights Act of 1964, 78 Stat. 252 (42 U.S.C. 2000d, 2000d-1))

[29 FR 16298, Dec. 4, 1964, as amended at 38 FR 17981, 17982, July 5, 1973]

§ 80.8 Procedure for effecting compliance.

(a) *General.* If there appears to be a failure or threatened failure to comply with this regulation, and if the noncompliance or threatened noncompliance cannot be corrected by informal means, compliance with this part may be effected by the suspension or termination of or refusal to grant or to continue Federal financial assistance or by any other means authorized by law. Such other means may include, but are not limited to, (1) a reference to the Department of Justice with a recommendation that appropriate proceedings be brought to enforce any rights of the United States under any law of the United States (including other titles of the Act), or any assurance or other contractual undertaking, and (2) any applicable proceeding under State or local law.

(b) *Noncompliance with § 80.4.* If an applicant fails or refuses to furnish an assurance required under § 80.4 or otherwise fails or refuses to comply with a requirement imposed by or pursuant to that section Federal financial assistance may be refused in accordance with the procedures of paragraph (c) of this section. The Department shall not be required to provide assistance in such a case during the pendency of the administrative proceedings under such paragraph except that the Department shall continue assistance during the pendency of such proceedings where such assistance is due and payable pursuant to an application therefor approved prior to the effective date of this part.

(c) *Termination of or refusal to grant or to continue Federal financial assistance.* No order suspending, terminating or refusing to grant or continue Federal financial assistance shall become effective until (1) the responsible Department official has advised the applicant or recipient of his failure to comply and has determined that compliance cannot be secured by voluntary means, (2) there has been an express finding on the record, after opportunity for hearing, of a failure by the applicant or recipient to comply with a requirement imposed by or pursuant to this part, (3) the expiration of 30 days after the Secretary has filed with the committee of the House and the committee of the Senate having legislative jurisdiction over the program involved, a full written report of the circumstances and the grounds for such action. Any action to suspend or terminate or to refuse to grant or to continue Federal financial assistance shall be limited to the particular political entity, or part thereof, or other applicant or recipient as to whom such a finding has been made and shall be limited in its effect to the particular program, or part thereof, in which such noncompliance has been so found.

(d) *Other means authorized by law.* No action to effect compliance by any other means authorized by law shall be taken until (1) the responsible Department official has determined that compliance cannot be secured by voluntary means, (2) the recipient or other person has been notified of its failure to comply and of the action to be taken to effect compliance, and (3) the expiration of at least 10 days from the mailing of such notice to the recipient or other person. During this period of at least 10 days additional efforts shall be made to persuade the recipient or other person to comply with the regulation and to take such corrective action as may be appropriate.

(Secs. 601, 602, Civil Rights Act of 1964, 78 Stat. 252 (42 U.S.C. 2000d, 2000d-1; sec. 182, 80 Stat. 1209; (42 U.S.C. 2000d-5))

[29 FR 16298, Dec. 4, 1964, as amended at 32 FR 14556, Oct. 19, 1967; 38 FR 17982, July 5, 1973]

§ 80.9 Hearings.

(a) *Opportunity for hearing.* Whenever an opportunity for a hearing is required by § 80.8(c), reasonable notice shall be given by registered or certified mail, return receipt requested, to the affected applicant or recipient. This notice shall advise the applicant or recipient of the action proposed to be taken, the specific provision under which the proposed action against it is to be taken, and the matters of fact or law asserted as the basis for this action, and either (1) fix a date not less than 20 days after the date of such notice within which the applicant or recipient may request of the responsible Department official that the matter be scheduled for hearing or (2) advise the applicant or recipient that the matter in question has been set down for hearing at a stated place and time. The time and place so fixed shall be reasonable and shall be subject to change for cause. The complainant, if any, shall be advised of the time and place of the hearing. An applicant or recipient may waive a hearing and submit written information and argument for the record. The failure of an applicant or recipient to request a hearing for which a date has been set shall be deemed to be a waiver of the right to a hearing under section 602 of the Act and § 80.8(c) of this regulation and consent to the making of a decision on the basis of such information as may be filed as the record.

(b) *Time and place of hearing.* Hearings shall be held at the offices of the Department in Washington, D.C., at a time fixed by the responsible Department official unless he determines that the convenience of the applicant or recipient or of the Department requires that another place be selected. Hearings shall be held before a hearing examiner designated in accordance with 5 U.S.C. 3105 and 3344 (section 11 of the Administrative Procedure Act).

(c) *Right to counsel.* In all proceedings under this section, the applicant or recipient and the Department shall have the right to be represented by counsel.

(d) *Procedures, evidence, and record.* (1) The hearing, decision, and any administrative review thereof shall be conducted in conformity with sections 5-8 of the Administrative Procedure Act, and in accordance with such rules of procedure as are proper (and not inconsistent with this section) relating to the conduct of the hearing, giving of notices subsequent to those provided for in paragraph (a) of this section, taking of testimony, exhibits, arguments and briefs, requests for findings, and other related matters. Both the Department and the applicant or recipient shall be entitled to introduce all relevant evidence on the issues as stated in the notice for hearing or as determined by the officer conducting the hearing at the outset of or during the hearing. Any person (other than a Government employee considered to be on official business) who, having been invited or requested to appear and testify as a witness on the Government's behalf, attends at a time and place scheduled for a hearing provided for by this part, may be reimbursed for his travel and actual expenses of attendance in an amount not to exceed the amount payable under the standardized travel regulations to a Government employee traveling on official business.

(2) Technical rules of evidence shall not apply to hearings conducted pursuant to this part, but rules or principles designed to assure production of the most credible evidence available and to subject testimony to test by cross-examination shall be applied where reasonably necessary by the officer conducting the hearing. The hearing officer may exclude irrelevant, immaterial, or unduly repetitious evidence. All documents and other evidence offered or taken for the record shall be open to examination by the parties and opportunity shall be given to refute facts and arguments advanced on either side of the issues. A transcript shall be made of the oral evidence except to the extent the substance thereof is stipulated for the record. All decisions shall be based upon the hearing record and written findings shall be made.

(e) *Consolidated or Joint Hearings.* In cases in which the same or related facts are asserted to constitute noncompliance with this regulation with respect to two or more programs to which this part applies, or noncompliance with this part and the regulations of one or more other Federal departments or agencies issued under Title VI of the Act, the responsible Department official may, by agreement with such other departments or agencies where applicable, provide for the conduct of consolidated or joint hearings, and for the application to such hearings of rules of procedures not inconsistent with this part. Final decisions in such cases, insofar as this regulation is concerned, shall be made in accordance with § 80.10.

(Sec. 602, Civil Rights Act of 1964, 78 Stat. 252 (42 U.S.C. 2000d-1))

[29 FR 16298, Dec. 4, 1964, as amended at 32 FR 14555, Oct. 19, 1967; 38 FR 17981, 17982, July 5, 1973]

§ 80.10 Decisions and notices.

(a) *Decisions by hearing examiners.* After a hearing is held by a hearing examiner such hearing examiner shall either make an initial decision, if so authorized, or certify the entire record including his recommended findings and proposed decision to the reviewing authority for a final decision, and a copy of such initial decision or certification shall be mailed to the applicant or recipient and to the complainant, if any. Where the initial decision referred to in this paragraph or in paragraph (c) of this section is made by the hearing examiner, the applicant or recipient or the counsel for the Department may, within the period provided for in the rules of procedure issued by the responsible Department official, file with the reviewing authority exceptions to the initial decision, with his reasons therefor. Upon the filing of such exceptions the reviewing authority shall review the initial decision and issue its own decision thereof including the reasons therefor. In the absence of exceptions the initial decision shall constitute the final decision, subject to the provisions of paragraph (e) of this section.

(b) *Decisions on record or review by the reviewing authority.* Whenever a record is certified to the reviewing authority for decision or it reviews the decision of a hearing examiner pursuant to paragraph (a) or (c) of this section, the applicant or recipient shall be given reasonable opportunity to file with it briefs or other written statements of its contentions, and a copy of the final decision of the reviewing authority shall be given in writing to the applicant or recipient and to the complainant, if any.

(c) *Decisions on record where a hearing is waived.* Whenever a hearing is waived pursuant to § 80.9(a) the reviewing authority shall make its final decision on the record or refer the matter to a hearing examiner for an initial decision to be made on the record. A copy of such decision shall be given in writing to the applicant or recipient, and to the complainant, if any.

(d) *Rulings required.* Each decision of a hearing examiner or reviewing authority shall set forth a ruling on each finding, conclusion, or exception presented, and shall identify the requirement or requirements imposed by or pursuant to this part with which it is found that the applicant or recipient has failed to comply.

(e) *Review in certain cases by the Secretary.* If the Secretary has not personally made the final decision referred to in paragraph (a), (b), or (c) of this section, a recipient or applicant or the counsel for the Department may request the Secretary to review a decision of the Reviewing Authority in accordance with rules of procedure issued by the responsible Department official. Such review is not a matter of right and shall be granted only where the Secretary determines there are special and important reasons therefor. The Secretary may grant or deny such request, in whole or in part. He may also review such a decision upon his own motion in accordance with rules of procedure issued by the responsible Department official. In the absence of a review under this paragraph, a final decision referred to in paragraphs (a), (b), and (c) of this section shall become the final decision of the Department when the Secretary transmits it as such to Congressional committees with the report required under section 602 of the Act. Failure of an applicant or recipient to file an exception with the Reviewing Authority or to request review under this paragraph shall not be deemed a failure to exhaust administrative remedies for the purpose of obtaining judicial review.

(f) *Content of orders.* The final decision may provide for suspension or termination of, or refusal to grant or continue Federal financial assistance, in whole or in part, to which this regulation applies, and may contain such terms, conditions, and other provisions as are consistent with and will effectuate the purposes of the Act and this regulation, including provisions designed to assure that no Federal financial assistance to which this regulation applies will thereafter be extended under such law or laws to the applicant or recipient determined by such decision to be in default in its performance of an assurance given by it pursuant to this regulation, or to have otherwise failed to comply with this regulation unless and until it corrects its noncompliance and satisfies the responsible Department official that it will fully comply with this regulation.

(g) *Post-termination proceedings.* (1) An applicant or recipient adversely affected by an order issued under paragraph (f) of this section shall be restored to full eligibility to receive Federal financial assistance if it satisfies the terms and conditions of that order for such eligibility or if it brings itself into compliance with this part and provides reasonable assurance that it will fully comply with this part. An elementary or secondary school or school system which is unable to file an assurance of compliance with § 80.3 shall be restored to full eligibility to receive Federal financial assistance, if it files a court order or a plan for desegregation which meets the requirements of § 80.4(c), and provides reasonable assurance that it will comply with the court order or plan.

(2) Any applicant or recipient adversely affected by an order entered pursuant to paragraph (f) of this section may at any time request the responsible Department official to restore fully its eligibility to receive Federal financial assistance. Any such request shall be supported by information showing that the applicant or recipient has met the requirements of paragraph (g)(1) of this section. If the responsible Department official determines that those requirements have been satisfied, he shall restore such eligibility.

(3) If the responsible Department official denies any such request, the applicant or recipient may submit a request for a hearing in writing, specifying why it believes such official to have been in error. It shall thereupon be given an expeditious hearing, with a decision on the record, in accordance with rules of procedure issued by the

responsible Department official. The applicant or recipient will be restored to such eligibility if it proves at such hearing that it satisfied the requirements of paragraph (g)(1) of this section. While proceedings under this paragraph are pending, the sanctions imposed by the order issued under paragraph (f) of this section shall remain in effect.

(Sec. 602, Civil Rights Act of 1964, 78 Stat. 252 (42 U.S.C. 2000d-1))

[29 FR 16298, Dec. 4, 1964, as amended at 32 FR 14555, Oct. 19, 1967; 38 FR 17981, 17982, July 5, 1973]

§ 80.11 Judicial review.

Action taken pursuant to section 602 of the Act is subject to judicial review as provided in section 603 of the Act.

(Sec. 603, 78 Stat. 253, (42 U.S.C. 2000d-2))

[29 FR 16298, Dec. 4, 1964, as amended at 32 FR 14556, Oct. 19, 1967]

§ 80.12 Effect on other regulations, forms and instructions.

(a) *Effect on other regulations.* All regulations, orders, or like directions heretofore issued by any officer of the Department which impose requirements designed to prohibit any discrimination against individuals on the ground of race, color, or national origin under any program to which this regulation applies, and which authorize the suspension or termination of or refusal to grant or to continue Federal financial assistance to any applicant for or recipient of assistance for failure to comply with such requirements, are hereby superseded to the extent that such discrimination is prohibited by this regulation, except that nothing in this regulation shall be deemed to relieve any person of any obligation assumed or imposed under any such superseded regulation, order, instruction, or like direction prior to the effective date of this regulation. Nothing in this regulation, however, shall be deemed to supersede any of the following (including future amendments thereof): (1) The "Standards for a Merit System of Personnel Administration," issued jointly by the Secretaries of Defense, of Health and Human Services, and of Labor, 45 CFR Part 70; (2) Executive Order 11063 and regulations issued thereunder, or any other regulations or instructions, insofar as such Order, regulations, or instructions prohibit discrimination on the ground of race, color, or national origin in any program or situation to which this regulation is inapplicable, or prohibit discrimination on any other ground; or (3) requirements for Emergency School Assistance as published in 35 FR 13442 and codified as 45 CFR Part 181.

(b) *Forms and instructions.* The responsible Department official shall issue and promptly make available to interested persons forms and detailed instructions and procedures for effectuating this part.

(c) *Supervision and coordination.* The responsible Department official may from time to time assign to officials of the Department, or to officials of other departments or agencies of the Government with the consent of such departments or agencies, responsibilities in connection with the effectuation of the purposes of Title VI of the Act and this regulation (other than responsibility for review as provided in § 80.10(e)), including the achievements of effective coordination and maximum uniformity within the Department and within the Executive Branch of the Government in the application of Title VI and this regulation to similar programs and in similar situations. Any action taken, determination made, or requirement imposed by an official of another Department or Agency acting pursuant to an assignment of responsibility under this subsection shall have the same effect as though such action had been taken by the responsible official of this Department.

(Sec. 602, Civil Rights Act of 1964, 78 Stat. 252 (42 U.S.C. 2000d-10))

[29 FR 16298, Dec. 4, 1964, as amended at 32 FR 14555, Oct. 19, 1967; 38 FR 17981, 17982, July 5, 1973]

§ 80.13 Definitions.

As used in this part—

(a) The term "Department" means the Department of Health and Human Services, and includes each of its operating agencies and other organizational units.

(b) The term "Secretary" means the Secretary of Health and Human Services.

(c) The term "responsible Department official" means the Secretary or, to the extent of any delegation by the Secretary of authority to act in his stead under any one or more provisions of this part, any person or persons to whom the Secretary has heretofore delegated, or to whom the Secretary may hereafter delegate such authority.

(d) The term "reviewing authority" means the Secretary, or any person or persons (including a board or other body specially created for that purpose and also including the responsible Department official) acting pursuant to authority delegated by the Secretary to carry out responsibilities under § 80.10 (a) through (d).

(e) The term "United States" means the States of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, Wake Island, the Canal Zone, and the territories and possessions of the United States, and the term "State" means any one of the foregoing.

(f) The term "Federal financial assistance" includes (1) grants and loans of Federal funds, (2) the grant or donation of Federal property and interests in property, (3) the detail of Federal personnel, (4) the sale and lease of, and the permission to use (on other than a casual or transient basis), Federal property or any interest in such property without consideration or at a nominal consideration, or at a consideration which is reduced for the purpose of assisting the recipient, or in recognition of the public interest to be served by such sale or lease to the recipient, and (5) any Federal agreement, arrangement, or other contract which has as one of its purposes the provision of assistance.

(g) The term "program" includes any program, project, or activity for the provision of services, financial aid, or other benefits to individuals (including education or training, health, welfare, rehabilitation, housing, or other services, whether provided through employees of the recipient of Federal financial assistance or provided by others through contracts or other arrangements with the recipient, and including work opportunities and cash or loan or other assistance to individuals), or for the provison of facilities for furnishing services, financial aid or other benefits to individuals. The services, financial aid, or other benefits provided under a program receiving Federal financial assistance shall be deemed to include any services, financial aid, or other benefits provided with the aid of Federal financial assistance or with the aid of any non-Federal funds, property, or other resources required to be expended or made available for the program to meet matching requirements or other conditions which must be met in order to receive the Federal financial assistance, and to include any services, financial aid, or other benefits provided in or through a facility provided with the aid of Federal financial assistance or such non-Federal resources.

(h) The term "facility" includes all or any portion of structures, equipment, or other real or personal property or interests therein, and the provision of facilities includes the construction, expansion, renovation, remodeling, alteration or acquisition of facilities.

(i) The term "recipient" means any State, political subdivision of any State, or instrumentality of any State or political subdivision, any public or private agency, institution, or organization, or other entity, or any individual, in any State, to whom Federal financial assistance is extended, directly or through another recipient, for any program, including any successor, assign, or transferee thereof, but such term does not include any ultimate beneficiary under any such program.

(j) The term "primary recipient" means any recipient which is authorized or required to extend Federal financial assistance to another recipient for the purpose of carrying out a program.

(k) The term "applicant" means one who submits an application, request, or plan required to be approved by a Department official, or by a primary recipient, as a condition to eligibility for Federal financial assistance, and the term "application" means such an application, request, or plan.

(Sec. 602, Civil Rights Act of 1964, 78 Stat. 252 (42 U.S.C. 2000d-1))

[29 FR 16298, Dec. 4, 1964; 29 FR 16988, Dec. 11, 1964, as amended at 32 FR 14555, Oct. 19, 1967; 38 FR 17982, July 5, 1973]

APPENDIX A TO PART 80—FEDERAL FINANCIAL ASSISTANCE TO WHICH THESE REGULATIONS APPLY

Part 1. Assistance other than for State-Administered Continuing Programs

1. Loans for acquisition of equipment for academic subjects, and for minor remodeling (20 U.S.C. 445).

2. Construction of facilities for institutions of higher education (20 U.S.C. 701-758).

3. School Construction in federally-affected and in major disaster areas (20 U.S.C. 631-647).

4. Construction of educational broadcast facilities (47 U.S.C. 390-399).

5. Loan service of captioned films and educational media; research on, and production and distribution of, educational media for the handicapped, and training of persons in the use of such media for the handicapped (20 U.S.C. 1452).

6. Demonstration residential vocational education schools (20 U.S.C. 1321).

7. Research and related activities in education of handicapped children (20 U.S.C. 1441).

8. Educational research, dissemination and demonstration projects; research training and construction under the Cooperation Research Act (20 U.S.C. 331-332(b)).

9. Research in teaching modern foreign languages (20 U.S.C. 512).

10. Training projects for manpower development and training (42 U.S.C. 2601, 2602, 2610a-2610c).

11. Research and training projects in Vocational Education (20 U.S.C. 1281(a), 1282-1284).

12. Allowances to institutions training NDEA graduate fellows (20 U.S.C. 461-465).

13. Grants for training in librarianship (20 U.S.C. 1031-1033).

14. Grants for training personnel for the education of handicapped children (20 U.S.C. 1431).

15. Allowances for institutions training teachers and related educational personnel in elementary and secondary education, or post-secondary vocational education (20 U.S.C. 1111-1118).

16. Recruitment, enrollment, training and assignment of Teacher Corps personnel (20 U.S.C. 1101-1107a).

17. Operation and maintenance of schools in Federally-affected and in major disaster areas (20 U.S.C. 236-241; 241-1; 242-244).

18. Grants or contracts for the operation of training institutes for elementary or secondary school personnel to deal with special educational problems occasioned by desegregation (42 U.S.C. 2000c-3).

19. Grants for in-service training of teachers and other schools personnel and employment of specialists in desegregation problems (42 U.S.C. 2000c-4).

20. Higher education students loan program (Title II, National Defense Education Act, 20 U.S.C. 421-429).

21. Educational Opportunity grants and assistance for State and private programs of low-interest insured loans and State loans to students in institutions of higher education (Title IV, Higher Education Act of 1965, 20 U.S.C. 1061-1087).

22. Grants and contracts for the conduct of Talent Search, Upward Bound, and Special Services Programs (20 U.S.C. 1068).

23. Land-grant college aid (7 U.S.C. 301-308; 321-326; 328-331).

24. Language and area centers (Title VI, National Defense Education Act, 20 U.S.C. 511).

25. American Printing House for the Blind (20 U.S.C. 101-105).

26. Future Farmers of America (36 U.S.C. 271-391) and similar programs.

27. Science clubs (Pub. L. 85-875, 20 U.S.C. 2, note).

28. Howard University (20 U.S.C. 121-129).

29. Gallaudet College (31 D.C. Code, Ch. 10).

30. Establishment and operation of a model secondary school for the deaf by Gallaudet College (31 D.C. Code 1051-1053; 80 Stat. 1027-1028).

31. Faculty development programs, workshops and institutes (20 U.S.C. 1131-1132).

32. National Technical Institute for the Deaf (20 U.S.C. 681-685).

33. Institutes and other programs for training educational personnel (Parts D, E, and F, Title V, Higher Education Act of 1965) (20 U.S.C. 1119-1119c-4).

34. Grants and contracts for research and demonstration projects in librarianship (20 U.S.C. 1034).

35. Acquisition of college library resources (20 U.S.C. 1021-1028).

36. Grants for strengthening developing institutions of higher education (20 U.S.C. 1051-1054); National Fellowships for teaching at developing institutions (20 U.S.C. 1055), and grants to retired professors to teach at developing institutions (20 U.S.C. 1056).

37. College Work-Study Program (42 U.S.C. 2751-2757).

38. Financial assistance for acquisition of higher education equipment, and minor remodeling (20 U.S.C. 1121-1129).

39. Grants for special experimental demonstration projects and teacher training in adult education (20 U.S.C. 1208).

40. Grant programs for advanced and undergraduate international studies (20 U.S.C. 1171-1176; 22 U.S.C. 2452(b)).

41. Experimental projects for developing State leadership or establishment of special services (20 U.S.C. 865).

42. Grants to and arrangements with State educational and other agencies to meet special educational needs of migratory children of migratory agricultural workers (20 U.S.C. 241e(c)).

43. Grants by the Commissioner of Education to local educational agencies for supplementary educational centers and services; guidance, counseling, and testing (20 U.S.C. 841-844; 844b).

44. Resource centers for improvement of education of handicapped children (20 U.S.C. 1421) and centers and services for deaf-blind children (20 U.S.C. 1422).

45. Recruitment of personnel and dissemination of information on education of handicapped (20 U.S.C. 1433).

46. Grants for research and demonstrations relating to physical education or recreation for handicapped children (20 U.S.C. 1442) and training of physical educators and recreation personnel (20 U.S.C. 1434).

47. Dropout prevention projects (20 U.S.C. 887).

48. Bilingual education programs (20 U.S.C. 880b-880b-6).

49. Grants to agencies and organizations for Cuban refugees (22) U.S.C. 2601(b)(4).

50. Grants and contracts for special programs for children with specific learning disabilities including research and related activities, training and operating model centers (20 U.S.C. 1461).

51. Curriculum development in vocational and technical education (20 U.S.C. 1391).

52. Establishment, including construction, and operation of a National Center on Educational Media and Materials for the Handicapped (20 U.S.C. 1453).

53. Grants and contracts for the development and operation of experimental preschool and early education programs for handicapped (20 U.S.C. 1423).

54. Grants to public or private non-profit agencies to carry on the Follow Through Program in kindergarten and elementary schools (42 U.S.C. 2809 (a)(2)).

55. Grants for programs of cooperative education and grants and contracts for training and research in cooperative education (20 U.S.C. 1087a-1087c).

56. Grants and contracts to encourage the sharing of college facilities and resources (network for knowledge) (20 U.S.C. 1133-1133b).

57. Grants, contracts, and fellowships to improve programs preparing persons for public service and to attract students to public service (20 U.S.C. 1134-1134b).

58. Grants for the improvement of graduate programs (20 U.S.C. 1135-1135c).

59. Contracts for expanding and improving law school clinical experience programs (20 U.S.C. 1136-1136b).

60. Exemplary programs and projects in vocational education (20 U.S.C. 1301-1305).

61. Grants to reduce borrowing cost for construction of residential schools and dormitories (20 U.S.C. 1323).

62. Project grants and contracts for research and demonstration relating to new or improved health facilities and services (section 304, PHS Act, 42 U.S.C. 242b).

63. Grants for construction or modernization of emergency rooms of general hospitals (Title VI, Part C, PHS Act, 42 U.S.C. 291j).

64. Institutional and special projects grants to schools of nursing (sections 805-808, PHS Act, 42 U.S.C. 296d-296g).

65. Grants for construction and initial staffing of facilities for prevention and treatment of alcoholism (section 241-2, Community Mental Health Centers Act (42 U.S.C. 2688 f and g).

66. Grants for construction and initial staffing of specialized facilities for the treatment of alcoholics requiring care in such facilities (section 243, Community Mental Health Centers Act, 42 U.S.C. 2688h).

67. Special project grants for training programs, evaluation of existing treatment programs, and conduct of significant programs relating to treatment of alcoholics (section 246, Community Mental Health Centers Act, 42 U.S.C. 2688j-1).

68. Grants for construction and initial staff of treatment facilities for narcotic addicts (section 251, Community Mental Health Centers Act, 42 U.S.C. 2688m).

69. Special project grants for training programs, evaluation of existing treatment programs, and conduct of significant programs relating to treatment of narcotics addicts (section 252, Community Mental Health Centers Act, 42 U.S.C. 2688n-1).

70. Grants for consultation services for Community Mental Health Centers, alcoholism prevention and treatment facilities for narcotic addicts, and facilities for mental health of children (section 264, Community Mental Health Centers Act, 42 U.S.C. 2688r).

71. Grants for construction and initial staff of facilities for mental health of children (section 271, Community Mental Health Centers Act, 42 U.S.C. 2688u).

72. Special project grants for training programs and evaluation of existing treatment program relating to mental health of chil-

dren (section 272, Community Mental Health Centers Act, 42 U.S.C. 2688x).

73. Grants and loans for construction and modernization of medical facilities in the District of Columbia (Pub. L. 90-457; 82 Stat. 631-3).

74. Teaching facilities for nurse training (sections. 801-804, Public Health Service Act, 42 U.S.C. 296-296c).

75. Teaching facilities for allied health professions personnel (section 791, Public Health Service Act, 42 U.S.C. 295h).

76. Mental retardation research facilities (Title VI, Part D, Public Health Service Act, 42 U.S.C. 295-395e).

77. George Washington University Hospital construction (76 Stat. 83, Pub. L. 87-460, May 31, 1962).

78. Research projects, including conferences, communication activities and primate or other center grants (sections 301, 303, 304, and 308, Public Health Service Act, 42 U.S.C. 241, 242a, 242b, and 242f).

79. General research support (section 301(d), Public Health Service Act, 42 U.S.C. 241).

80. Mental Health demonstrations and administrative studies (section 303(a)(2), Public Health Service Act, 42 U.S.C. 242a).

81. Migratory workers health services (section 310, Public Health Service Act, 42 U.S.C. 242h).

82. Immunization programs (section 317, Public Health Service Act, 42 U.S.C. 247b).

83. Health research training projects and fellowship grants (sections 301, 433, Public Health Service Act, 42 U.S.C. 242, 289c).

84. Categorical (heart, cancer, etc.) grants for training, traineeships or fellowships (sections 303, 433, etc., Public Health Service Act, 42 U.S.C. 242a, 289c, etc.).

85. Advanced professional nurse traineeships (section 821, Public Health Service Act, 42 U.S.C. 297).

86. Department projects under Appalachian Regional Development Act (40 U.S.C. App. A).

87. Grants to institutions for traineeships for professional public health personnel section 306, Public Health Service Act, 42 U.S.C. 242d).

88. Grants for graduate or specialized training in public health (section 309, Public Health Service Act, 42 U.S.C. 242g).

89. Health professions school student loan program (Title VII, Part C, Public Health Service Act, 42 U.S.C. 294-294(k)).

90. Grants for provision in schools of public health of training, consultation and technical assistance in the field of public health and in the administration of state or local public health programs (section 309(c)), Public Health Service Act, 42 U.S.C. 242(g)(c)).

91. Project grants for training, studies, or demonstrations looking metropolitan area, or other local area plans for health services (section 314(c), Public Health Service Act, 42 U.S.C. 246(c)).

92. Project grants for training, studies, or demonstrations looking toward the development of improved comprehensive health planning (section 314(c), Public Health Service Act, 42 U.S.C. 246(c)).

93. Project grants for health services development (section 314(e), Public Health Service Act, 42 U.S.C. 246(e)).

94. Institutional and special grants to health professions schools (Title VII, Part E, Public Health Service Act, 42 U.S.C. 295f-295f-4).

95. Improvement grants to centers for allied health professions (section 792, Public Health Service Act, 42 U.S.C. 295h-1).

96. Scholarship grants to health professions schools (Title VII, Part F, Public Health Service Act, 42 U.S.C. 295h-1).

97. Scholarship grants to schools of nursing (Title VIII, Part D, Public Health Service Act, 42 U.S.C. 198c-298c-6).

98. Traineeships for advanced training of allied health professions personnel (section 793, Public Health Service Act, 42 U.S.C. 295h-2).

99. Contracts to encourage full utilization of nursing educational talent (section 868, Public Health Service Act, 42 U.S.C. 298c-7).

100. Grants to community mental health centers for the compensation of professional and technical personnel for the initial operation of new centers or of new services in centers (Community Mental Health Centers Act, Part B, 42 U.S.C. 2688-2688d).

101. Grants for the planning, construction, equipment and operation of multicounty demonstration health projects in the Appalachian region (section 202 of Appalachian Regional Development Act, Pub. L. 89-4, as amended, Pub. L. 90-103 40 U.S.C. App. 202).

102. Education, research, training, and demonstrations in the fields of heart disease, cancer, stroke and related diseases (sections 900-110, Public Health Service Act, 42 U.S.C. 299a-j).

103. Assistance to medical libraries (sections 390-399, Public Health Service Act, 42 U.S.C. 280b-280b-9).

104. Nursing student loans (sections 822-828. Public Health Service Act, 42 U.S.C. 297a-g).

105. Hawaii leprosy payments (section 331, Public Health Service Act, 42 U.S.C. 255).

106. Heart disease laboratories and related facilities for patient care (section 412(d), Public Health Service Act, 42 U.S.C. 287a(d)).

107. Grants for construction of hospitals serving Indians (Pub. L. 85-151, 42 U.S.C. 2005).

108. Indian Sanitation Facilities (Pub. L. 86-121, 42 U.S.C. 2004a).

109. Research projects relating to maternal and child health services and crippled children's services (42 U.S.C. 712).

110. Maternal and child health special project grants to State agencies and institutions of higher learning (42 U.S.C. 703(s)).

111. Maternity and infant care and family planning services; special project grants to local health agencies and other organizations (42 U.S.C. 708).

112. Special project grants to State agencies and institutions of higher learning for crippled children's services (42 U.S.C. 704(2)).

113. Special project grants for health of school and preschool children (42 U.S.C. 709) and for dental health of children (42 U.S.C. 710).

114. Grants to institutions of higher learning for training personnel for health care and related services for mothers and children (42 U.S.C. 711).

115. Grants and contracts for the conduct of research, experiments, or demonstrations relating to the developments, utilization, quality, organization, and financing of services, facilities, and resources of hospitals, long-term care facilities, for other medical facilities (section 304, Public Health Service Act, as amended by Pub. L. 90-174, 42 U.S.C. 242b).

116. Health research facilities (Title VII Part A, Public Health Service Act, 42 U.S.C. 292-292j).

117. Teaching facilities for health professions personnel (Title VII, Part B, Public Health Service Act, 42 U.S.C. 293-293h).

118. Project grants and contracts for research, development, training, and studies in the field of electronic product radiation (section 356, Public Health Service Act, 42 U.S.C. 263d).

119. Project grants and contracts for research, studies, demonstrations, training, and education relating to coal mine health (section 501, Federal Coal Mine Health and Safety Act of 1969, Public Law 91-173).

120. Surplus real and related personal property disposal (40 U.S.C. 484(k)).

121. Supplementary medical insurance benefits for the aged (Title XVIII, Part A, Social Security Act, 42 U.S.C. 1395c-1395i-2).

122. Issuance of rent-free permits for vending stands, credit unions, employee associations, etc. (20 U.S.C. 107-107f; 45 C.F.R. Part 20; section 25, 12 U.S.C. 1170).

123. Grants for special vocational rehabilitation projects (29 U.S.C. 34(a)(1)).

124. Experimental, pilot or demonstration projects to promote the objectives of Title I, X, XIV, XVI, or XIX or Part A of Title IV of the Social Security Act (42 U.S.C. 1315).

125. Social Security and welfare cooperative research or demonstration projects (42 U.S.C. 1310).

126. Child welfare research, training or demonstration projects (42 U.S.C. 626).

127. Training projects (Title VI, Older Americans Act, 42 U.S.C. 3041-3042).

128. Grants for expansion of vocational rehabilitation services (29 U.S.C. 34(a)(2)(A)).

129. Grants for construction of rehabilitation facilities (29 U.S.C. 41a(a)-(e)) and for initial staffing of rehabilitation facilities (29 U.S.C. 41a(f)).

130. Project development grants for rehabilitation facilities (29 U.S.C. 41a(g)(2)).

131. Rehabilitation Facility improvement grants (29 U.S.C. 41b(b)).

132. Agreement for the establishment and operation of a national center for deaf-blind youths and adults (29 U.S.C. 42a).

133. Project grants for services for migratory agricultural workers (29 U.S.C. 42b).

134. Grants for initial staffing of community mental retardation facilities (42 U.S.C. 2678-2678d).

135. Grants for training welfare personnel and for expansion and development of undergraduate and graduate social work programs (42 U.S.C. 906, 908).

136. Research and development projects concerning older Americans (42 U.S.C. 3031-3032).

137. Grants to States for training of nursing home administrators (42 U.S.C. 1396g (e)).

138. Contracts or jointly financed cooperative arrangements with industry (29 U.S.C. 34(a)(2)(B)).

139. Project grants for new careers in rehabilitation (29 U.S.C. 34(a)(2)(C)).

140. Children of low-income families (20 U.S.C. 241a-241m).

141. Grants for training (29 U.S.C. 37(a) (2)).

142. Grants for projects for training services (29 U.S.C. 41b(a)).

143. Grants for comprehensive juvenile delinquency planning (42 U.S.C. 3811).

144. Grants for project planning in juvenile delinquency (42 U.S.C. 3812).

145. Grants for juvenile delinquency rehabilitative services projects (42 U.S.C. 3822, 3842).

146. Grants for juvenile delinquency preventive service projects (42 U.S.C. 3861).

147. Grants for training projects in juvenile delinquency fields (42 U.S.C. 3861).

148. Grants for development of improved techniques and practices in juvenile delinquency services (42 U.S.C. 3871).

149. Grants for technical assistance in juvenile delinquency services (42 U.S.C. 3872).

150. Grants for State technical assistance to local units in juvenile delinquency services (42 U.S.C. 3873).

151. Grants for public service centers projects (42 U.S.C. 2744).

152. Grants to public or private non-profit agencies to carry on the Project Headstart Program (42 U.S.C. 2809(a)(1)).

153. Project grants for new careers for the handicapped (29 U.S.C. 34(a)(2)(D)).

154. Construction, demonstration, and training grants for university-affiliated facilities for persons with developmental disabilities (42 U.S.C. 2661–2666).

Part 2. Continuing Assistance to State Administered Programs.

1. Grants to States for public library services and construction, interlibrary cooperation and specialized State library services for certain State institutions and the physically handicapped (20 U.S.C. 351–355).

2. Grants to States for strengthening instruction in academic subjects (20 U.S.C. 441–444).

3. Grants to States for vocational education (20 U.S.C. 1241–1264).

4. Arrangements with State education agencies for training under the Manpower Development and Training Act (42 U.S.C. 2601–2602, 2610a).

5. Grants to States to assist in the elementary and secondary education of children of low-income families (20 U.S.C. 241a–241m).

6. Grants to States to provide for school library resources, textbooks and other instructional materials for pupils and teachers in elementary and secondary schools (20 U.S.C. 821–827).

7. Grants to States to strengthen State departments of education (20 U.S.C. 861–870).

8. Grants to States for community service programs (20 U.S.C. 1001–1011).

9. Grants to States for adult basic education and related research, teacher training and special projects (20 U.S.C. 1201–1211).

10. Grants to State educational agencies for supplementary educational centers and services, and guidance, counseling and testing (20 U.S.C. 841–847).

11. Grants to States for research and training in vocational education (20 U.S.C. 1281(b)).

12. Grants to States for exemplary programs and projects in vocational education (20 U.S.C. 1301–1305).

13. Grants to States for residential vocational education schools (20 U.S.C. 1321).

14. Grants to States for consumer and homemaking education (20 U.S.C. 1341).

15. Grants to States for cooperative vocational educational program (20 U.S.C. 1351–1355).

16. Grants to States for vocational work-study programs (20 U.S.C. 1371–1374).

17. Grants to States to attract and qualify teachers to meet critical teaching shortages (20 U.S.C. 1108–1110c).

18. Grants to States for education of handicapped children (20 U.S.C. 1411–1414).

19. Grants for administration of State plans and for comprehensive planning to determine construction needs of institutions of higher education (20 U.S.C. 715(b)).

20. Grants to States for comprehensive health planning (section 314(a), Public Health Service Act, 42 U.S.C. 246(a)).

21. Grants to States for establishing and maintaining adequate public health services (section 314(d), Public Health Service Act, 42 U.S.C. 246(d)).

22. Grants, loans, and loan guarantees with interest subsidies for hospital and medical facilities (Title VI, Public Health Service Act, 42 U.S.C. 291 et seq.).

23. Grants to States for community mental health centers construction (Community Mental Health Centers Act, Part A, 42 U.S.C. 2681–2687).

24. Cost of rehabilitation services (Title II, Social Security Act section 222(d); 42 U.S.C. 422(d)).

25. Surplus personal property disposal donations for health and educational purposes through State agencies (40 U.S.C. 484(j)).

26. Grants for State and community programs on aging (Title III, Older Americans Act, 42 U.S.C. 3021–3025).

27. Grants to States for planning, provision of services, and construction and operation of facilities for persons with developmental disabilities (42 U.S.C. 2670–2677c).

28. Grants to States for vocational rehabilitation services (29 U.S.C. 32); for innovation of vocational rehabilitation services (29 U.S.C. 33); and for rehabilitation facilities planning (29 U.S.C. 41a(g)(1)).

29. Designation of State licensing agency for blind operators of vending stands (20 U.S.C. 107–107f).

30. Grants to States for old-age assistance (42 U.S.C. 301 et seq.); aid to families with dependent children (42 U.S.C. 601 et seq.); child-welfare services (42 U.S.C. 620 et seq.); aid to the blind (42 U.S.C. 1201 et seq.); aid to the permanently and totally disabled (42 U.S.C. 1351 et seq.); aid to the aged, blind, or disabled (42 U.S.C. 1381 et seq.); medical assistance (42 U.S.C. 1396 et seq.).

31. Grants to States for maternal and child health and crippled children's services (42 U.S.C. 701–707); for special projects for maternal and infant care (42 U.S.C. 708).

32. Grants to States for juvenile delinquency preventive and rehabilitative services (42 U.S.C. 3841).

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APPENDIX B TO PART 80—GUIDELINES FOR ELIMINATING DISCRIMINATION AND DENIAL OF SERVICES ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, SEX, AND HANDICAP IN VOCATIONAL EDUCATION PROGRAMS

I. SCOPE AND COVERAGE

A. APPLICATION OF GUIDELINES

These Guidelines apply to recipients of any Federal financial assistance from the Department of Health and Human Services that offer or administer programs of vocational education or training. This includes State agency recipients.

B. DEFINITION OF RECIPIENT

The definition of "recipient" of Federal financial assistance is established by Department regulations implementing Title VI, Title IX, and Section 504 (45 CFR 80.13(i), 86.2(h), 84.3(f).

For the purposes of Title VI:

The term "recipient" means any State, political subdivision of any State, or instrumentality of any State or political subdivision, any public or private agency, institution, or organization, or other entity, or any individual, in any State, to whom Federal financial assistance is extended, directly or through another recipient, for any program, including any successor, assignee, or transferee thereof, but such term does not include any ultimate beneficiary [e.g., students] under any such program. (45 CFR 80.13(i)).

For the purpose of Title IX:

"Recipient" means any State or political subdivision thereof, or any instrumentality of a State or political subdivision thereof, any public or private agency, institution, or organization, or other entity, or any person to whom Federal financial assistance is extended directly or through another recipient and which operates an education program or activity which receives or benefits from such assistance, including any subunit, successor, assignee, or transferee thereof. (45 CFR 86.2(h)).

For the purposes of Section 504:

"Recipient" means any State or its political subdivision, any instrumentality of a State or its political subdivision, any public or private agency, institution, organization, or other entity, or any person to which Federal financial assistance is extended directly or through another recipient, including any successor, assignee, or transferee of a recipient, but excluding the ultimate beneficiary of the assistance. (45 CFR 84.3(f)).

C. EXAMPLES OF RECIPIENTS COVERED BY THESE GUIDELINES

The following education agencies, when they provide vocational education, are examples of recipients covered by these Guidelines:

1. The board of education of a public school district and its administrative agency.

2. The administrative board of a specialized vocational high school serving students from more than one school district.

3. The administrative board of a technical or vocation school that is used exclusively or principally for the provision of vocational education to persons who have completed or left high school (including persons seeking a certificate or an associate degree through a vocational program offered by the school) and who are available for study in preparation for entering the labor market.

4. The administrative board of a postsecondary institution, such as a technical institute, skill center, junior college, community college, or four year college that has a department or division that provides vocational education to students seeking immediate employment, a certificate or an associate degree.

5. The administrative board of a proprietary (private) vocational education school.

6. A State agency recipient itself operating a vocational education facility.

D. EXAMPLES OF SCHOOLS TO WHICH THESE GUIDELINES APPLY

The following are examples of the types of schools to which these Guidelines apply.

1. A junior high school, middle school, or those grades of a comprehensive high school that offers instruction to inform, orient, or prepare students for vocational education at the secondary level.

2. A vocational education facility operated by a State agency.

3. A comprehensive high school that has a department exclusively or principally used for providing vocational education; or that offers at least one vocational program to secondary level students who are available for study in preparation for entering the labor market; or that offers adult vocational education to persons who have completed or left high school and who are available for study in preparation for entering the labor market.

4. A comprehensive high school, offering the activities described above, that receives students on a contract basis from other school districts for the purpose of providing vocational education.

5. A specialized high school used exclusively or principally for the provision of vocational education, that enrolls students

from one or more school districts for the purpose of providing vocational education.

6. A technical or vocational school that primarily provides vocational education to persons who have completed or left high school and who are available for study in preparation for entering the labor market, including students seeking an associate degree or certificate through a course of vocational instruction offered by the school.

7. A junior college, a community college, or four-year college that has a department or division that provides vocational education to students seeking immediate employment, an associate degree or a certificate through a course of vocational instruction offered by the school.

8. A proprietary school, licensed by the State, that offers vocational education.

NOTE: Subsequent sections of these Guidelines may use the term *secondary vocational education center* in referring to the institutions described in paragraphs 3, 4 and 5 above or the term *postsecondary vocational education center* in referring to institutions described in paragraphs 6 and 7 above or the term *vocational education center* in referring to any or all institutions described above.

II. RESPONSIBILITIES ASSIGNED ONLY TO STATE AGENCY RECIPIENTS

A. RESPONSIBILITIES OF ALL STATE AGENCY RECIPIENTS

State agency recipients, in addition to complying with all other provisions of the Guidelines relevant to them, may not require, approve of, or engage in any discrimination or denial of services on the basis of race, color, national origin, sex, or handicap in performing any of the following activities:

1. Establishment of criteria or formulas for distribution of Federal or State funds to vocational education programs in the State;

2. Establishment of requirements for admission to or requirements for the administration of vocational education programs;

3. Approval of action by local entities providing vocational education. (For example, a State agency must ensure compliance with Section IV of these Guidelines if and when it reviews a vocational education agency decision to create or change a geographic service area.);

4. Conducting its own programs. (For example, in employing its staff it may not discriminate on the basis of sex or handicap.)

B. STATE AGENCIES PERFORMING OVERSIGHT RESPONSIBILITIES

The State agency responsible for the administration of vocational education programs must adopt a compliance program to prevent, identify and remedy discrimination on the basis of race, color, national origin, sex or handicap by its subrecipients. (A "subrecipient," in this context, is a local agency or vocational education center that receives financial assistance through a State agency.) This compliance program must include:

1. Collecting and analyzing civil rights related data and information that subrecipients compile for their own purposes or that are submitted to State and Federal officials under existing authorities;

2. Conducting periodic compliance reviews of selected subrecipients (i.e., an investigation of a subrecipient to determine whether it engages in unlawful discrimination in any aspect of its program); upon finding unlawful discrimination, notifying the subrecipient of steps it must take to attain compliance and attempting to obtain voluntary compliance;

3. Providing technical assistance upon request to subrecipients. This will include assisting subrecipients identify unlawful discrimination and instructing them in remedies for and prevention of such discrimination;

4. Periodically reporting its activities and findings under the foregoing paragraphs, including findings of unlawful discrimination under paragraph 2, immediately above, to the Office for Civil Rights.

State agencies are not required to terminate or defer assistance to any subrecipient. Nor are they required to conduct hearings. The responsibilities of the Office for Civil Rights to collect and analyze data, to conduct compliance reviews, to investigate complaints and to provide technical assistance are not diminished or attenuated by the requirements of Section II of the Guidelines.

C. STATEMENT OF PROCEDURES AND PRACTICES

Within one year from the publication of these Guidelines in final form, each State agency recipient performing oversight responsibilities must submit to the Office for Civil Rights the methods of administration and related procedures it will follow to comply with the requirements described in paragraphs A and B immediately above. The Department will review each submission and will promptly either approve it, or return it to State officials for revision.

III. DISTRIBUTION OF FEDERAL FINANCIAL ASSISTANCE AND OTHER FUNDS FOR VOCATIONAL EDUCATION

A. AGENCY RESPONSIBILITIES

Recipients that administer grants for vocational education must distribute Federal, State, or local vocational education funds so that no student or group of students is unlawfully denied an equal opportunity to benefit from vocational education on the basis of race, color, national origin, sex, or handicap.

B. DISTRIBUTION OF FUNDS

Recipients may not adopt a formula or other method for the allocation of Federal, State, or local vocational education funds that has the effect of discriminating on the basis of race, color, national origin, sex, or handicap. However, a recipient may adopt a formula or other method of allocation that uses as a factor race, color, national origin, sex, or handicap [or an index or proxy for race, color, national origin, sex, or handicap e.g., number of persons receiving Aid to Families with Dependent Children or with limited English speaking ability] if the factor is included to compensate for past discrimination or to comply with those provisions of the Vocational Education Amendments of 1976 designed to assist specified protected groups.

C. EXAMPLE OF A PATTERN SUGGESTING UNLAWFUL DISCRIMINATION

In each State it is likely that some local recipients will enroll greater proportions of minority students in vocational education than the State-wide proportion of minority students in vocational education. A funding formula or other method of allocation that results in such local recipients receiving per-pupil allocations of Federal or State vocational education funds lower than the State-wide average per-pupil allocation will be presumed unlawfully discriminatory.

D. DISTRIBUTION THROUGH COMPETITIVE GRANTS OR CONTRACTS

Each State agency that establishes criteria for awarding competitive vocational education grants or contracts must establish and apply the criteria without regard to the race, color, national origin, sex, or handicap of any or all of a recipient's students, except to compensate for past discrimination.

E. APPLICATION PROCESSES FOR COMPETITIVE OR DISCRETIONARY GRANTS

State agencies must disseminate information needed to satisfy the requirements of any application process for competitive or discretionary grants so that all recipients, including those having a high percentage of minority or handicapped students, are informed of and able to seek funds. State agencies that provide technical assistance for the completion of the application process must provide such assistance without discrimination against any one recipient or class of recipients.

F. ALTERATION OF FUND DISTRIBUTION TO PROVIDE EQUAL OPPORTUNITY

If the Office for Civil Rights finds that a recipient's system for distributing vocational education funds unlawfully discriminates on the basis of race, color, national origin, sex, or handicap, it will require the recipient to adopt an alternative nondiscriminatory method of distribution. The Office for Civil Rights may also require the recipient to compensate for the effects of its past unlawful discrimination in the distribution of funds.

IV. ACCESS AND ADMISSION OF STUDENTS TO VOCATIONAL EDUCATION PROGRAMS

A. RECIPIENT RESPONSIBILITIES

Criteria controlling student eligibility for admission to vocational education schools, facilities and programs may not unlawfully discriminate on the basis of race, color, national origin, sex, or handicap. A recipient may not develop, impose, maintain, approve, or implement such discriminatory admissions criteria.

B. SITE SELECTION FOR VOCATIONAL SCHOOLS

State and local recipients may not select or approve a site for a vocational education facility for the purpose or with the effect of excluding, segregating, or otherwise discriminating against students on the basis of race, color, or national origin. Recipients must locate vocational education facilities at sites that are readily accessible to both nonminority and minority communities, and that do not tend to identify the facility or program as intended for nonminority or minority students.

C. ELIGIBILITY FOR ADMISSION TO VOCATIONAL EDUCATION CENTERS BASED ON RESIDENCE

Recipients may not establish, approve or maintain geographic boundaries for a vocational education center service area or attendance zone, (hereinafter "service area"), that unlawfully exclude students on the basis of race, color, or national origin. The Office for Civil Rights will presume, subject to rebuttal, that any one or combination of the following circumstances indicates that the boundaries of a given service area are unlawfully constituted:

1. A school system or service area contiguous to the given service area, contains minority or nonminority students in substantially greater proportion than the given service area;

2. A substantial number of minority students who reside outside the given vocational education center service area, and who are not eligible for the center reside, nonetheless, as close to the center as a substantial number of non-minority students who are eligible for the center;

3. The over-all vocational education program of the given service area in comparison to the over-all vocational education pro-

gram of a contiguous school system or service area enrolling a substantially greater proportion of minority students: (a) Provides its students with a broader range of curricular offerings, facilities and equipment; or (b) provides its graduates greater opportunity for employment in jobs: (i) For which there is a demonstrated need in the community or region; (ii) that pay higher entry level salaries or wages; or (iii) that are generally acknowledged to offer greater prestige or status.

D. ADDITIONS AND RENOVATIONS TO EXISTING VOCATIONAL EDUCATION FACILITIES

A recipient may not add to, modify, or renovate the physical plant of a vocational education facility in a manner that creates, maintains, or increases student segregation on the basis of race, color, national origin, sex, or handicap.

E. REMEDIES FOR VIOLATIONS OF SITE SELECTION AND GEOGRAPHIC SERVICE AREA REQUIREMENTS

If the conditions specified in paragraphs IV, A, B, C, or D, immediately above, are found and not rebutted by proof of nondiscrimination, the Office for Civil rights will require the recipient(s) to submit a plan to remedy the discrimination. The following are examples of steps that may be included in the plan, where necessary to overcome the discrimination: (1) Redrawing of the boundaries of the vocational education center's service area to include areas unlawfully excluded and/or to exclude areas unlawfully included; (2) provision of transportation to students residing in areas unlawfully excluded; (3) provision of additional programs and services to students who would have been eligible for attendance at the vocational education center but for the discriminatory service area or site selection; (4) reassignment of students; and (5) construction of new facilities or expansion of existing facilities.

F. ELIGIBILITY FOR ADMISSION TO SECONDARY VOCATIONAL EDUCATION CENTERS BASED ON NUMERICAL LIMITS IMPOSED ON SENDING SCHOOLS

A recipient may not adopt or maintain a system for admission to a secondary vocational education center or program that limits admission to a fixed number of students from each sending school included in the center's service area if such a system disproportionately excludes students from the center on the basis of race, sex, national origin or handicap. (Example: Assume 25 percent of a school district's high school students are black and that most of those black students are enrolled in one high school; the white students, 75 percent of the district's total enrollment, are generally enrolled in the five remaining high schools. This paragraph prohibits a system of admission to the secondary vocational education center that limits eligibility to a fixed and equal number of students from each of the district's six high schools.)

G. REMEDIES FOR VIOLATION OF ELIGIBILITY BASED ON NUMERICAL LIMITS REQUIREMENTS

If the Office for Civil Rights finds a violation of paragraph F, above, the recipient must implement an alternative system of admissions that does not disproportionately exclude students on the basis of race, color, national origin, sex, or handicap.

H. ELIGIBILITY FOR ADMISSION TO VOCATIONAL EDUCATION CENTERS, BRANCHES OR ANNEXES BASED UPON STUDENT OPTION

A vocational education center, branch or annex, open to all students in a service area and predominantly enrolling minority students or students of one race, national origin or sex, will be presumed unlawfully segregated if: (1) It was established by a recipient for members of one race, national origin or sex; or (2) it has since its construction been attended primarily by members of one race, national origin or sex; or (3) most of its program offerings have traditionally been selected predominantely by members of one race, national origin or sex.

I. REMEDIES FOR FACILITY SEGREGATION UNDER STUDENT OPTION PLANS

If the conditions specified in paragraph IV-H are found and not rebutted by proof of nondiscrimination, the Office for Civil Rights will require the recipient(s) to submit a plan to remedy the segregation. The following are examples of steps that may be included in the plan, where necessary to overcome the discrimination:

(1) elimination of program duplication in the segregated facility and other proximate vocational facilities; (2) relocation or "clustering" of programs or courses; (3) adding programs and courses that traditionally have been identified as intended for members of a particular race, national origin or sex to schools that have traditionally served members of the other sex or traditionally served persons of a different race or national origin; (4) merger of programs into one facility through school closings or new construction; (5) intensive outreach recruitment and counseling; (6) providing free transportation to students whose enrollment would promote desegregation.

[Paragraph J omitted]

K. ELIGIBILITY BASED ON EVALUATION OF EACH APPLICANT UNDER ADMISSIONS CRITERIA

Recipients may not judge candidates for admission to vocational education programs on the basis of criteria that have the effect of disproportionately excluding persons of a particular race, color, national origin, sex, or handicap. However, if a recipient can demonstrate that such criteria have been validated as essential to participation in a given program and that alternative equally valid criteria that do not have such a disproportionate adverse effect are unavailable, the criteria will be judged nondiscriminatory. Examples of admissions criteria that must meet this test are past academic performance, record of disciplinary infractions, counselors' approval, teachers' recommendations, interest inventories, high school diplomas and standardized tests, such as the Test of Adult Basic Education (TABE).

An introductory, preliminary, or exploratory course may not be established as a prerequisite for admission to a program unless the course has been and is available without regard to race, color, national origin, sex, and handicap. However, a course that was formerly only available on a discriminatory basis may be made a prerequisite for admission to a program if the recipient can demonstrate that: (a) the course is essential to participation in the program; *and* (b) the course is presently available to those seeking enrollment for the first time and to those formerly excluded.

L. ELIGIBILITY OF NATIONAL ORIGIN MINORITY PERSONS WITH LIMITED ENGLISH LANGUAGE SKILLS

Recipients may not restrict an applicant's admission to vocational education programs because the applicant, as a member of a national origin minority with limited English language skills, cannot participate in and benefit from vocational instruction to the same extent as a student whose primary language is English. It is the responsibility of the recipient to identify such applicants and assess their ability to participate in vocational instruction.

Acceptable methods of identification include: (1) Identification by administrative staff, teachers, or parents of secondary level students; (2) identification by the student in postsecondary or adult programs; and (3) appropriate diagnostic procedures, if necessary.

Recipients must take steps to open all vocational programs to these national origin minority students. A recipient must demonstrate that a concentration of students with limited English language skills in one or a few programs is not the result of discriminatory limitations upon the opportunities available to such students.

M. REMEDIAL ACTION IN BEHALF OF PERSONS WITH LIMITED ENGLISH LANGUAGE SKILLS

If the Office for Civil Rights finds that a recipient has denied national origin minority persons admission to a vocational school or program because of their limited English language skills or has assigned students to vocational programs solely on the basis of their limited English language skills, the recipient will be required to submit a remedial plan that insures national origin minority students equal access to vocational education programs.

N. EQUAL ACCESS FOR HANDICAPPED STUDENTS

Recipients may not deny handicapped students access to vocational education programs or courses because of architectural or equipment barriers, or because of the need for related aids and services or auxiliary aids. If necessary, recipients must: (1) Modify instructional equipment; (2) modify or adapt the manner in which the courses are offered; (3) house the program in facilities that are readily accessible to mobility impaired students or alter facilities to make them readily accessible to mobility impaired students; and (4) provide auxiliary aids that effectively make lectures and necessary materials available to postsecondary handicapped students; (5) provide related aids or services that assure secondary students an appropriate education.

Academic requirements that the recipient can demonstrate are essential to a program of instruction or to any directly related licensing requirement will not be regarded as discriminatory. However, where possible, a recipient must adjust those requirements to the needs of individual handicapped students.

Access to vocational programs or courses may not be denied handicapped students on the ground that employment opportunities in any occupation or profession may be more limited for handicapped persons than for non-handicapped persons.

O. PUBLIC NOTIFICATION

Prior to the beginning of each school year, recipients must advise students, parents, employees and the general public that all vocational opportunities will be offered without regard to race, color, national origin, sex, or handicap. Announcement of this policy of non-discrimination may be made, for example, in local newspapers, recipient publications and/or other media that reach the general public, program beneficiaries, minorities (including national origin minorities with limited English language skills), women, and handicapped persons. A brief summary of program offerings and admission criteria should be included in the announcement; also the name, address and telephone number of the person designated to coordinate Title IX and Section 504 compliance activity.

If a recipient's service area contains a community of national origin minority persons with limited English language skills, public notification materials must be disseminated to that community in its language and must state that recipients will take steps to assure that the lack of English language skills will not be a barrier to admission and participation in vocational education programs.

V. COUNSELING AND PREVOCATIONAL PROGRAMS

A. RECIPIENT RESPONSIBILITIES

Recipients must insure that their counseling materials and activities (including student program selection and career/employment selection), promotional, and recruitment efforts do not discriminate on the basis of race, color, national origin, sex, or handicap.

B. COUNSELING AND PROSPECTS FOR SUCCESS

Recipients that operate vocational education programs must insure that counselors do not direct or urge any student to enroll in a particular career or program, or measure or predict a student's prospects for success in in any career or program based upon the student's race, color, national origin, sex, or handicap. Recipients may not counsel handicapped students toward more restrictive career objectives than nonhandicapped students with similar abilities and interests. If a vocational program disproportionately enrolls male or female students, minority or nonminority students, or handicapped students, recipients must take steps to insure that the disproportion does not result from unlawful discrimination in counseling activities.

C. STUDENT RECRUITMENT ACTIVITIES

Recipients must conduct their student recruitment activities so as not to exclude or limit opportunities on the basis of race, color, national origin, sex, or handicap. Where recruitment activities involve the presentation or portrayal of vocational and career opportunities, the curricula and programs described should cover a broad range of occupational opportunities and not be limited on the basis of the race, color, national origin, sex, or handicap of the students or potential students to whom the presentation is made. Also, to the extent possible, recruiting teams should include persons of different races, national origins, sexes, and handicaps.

D. COUNSELING OF STUDENTS WITH LIMITED ENGLISH-SPEAKING ABILITY OR HEARING IMPAIRMENTS

Recipients must insure that counselors can effectively communicate with national origin minority students with limited English language skills and with students who have hearing impairments. This requirement may be satisfied by having interpreters available.

E. PROMOTIONAL ACTIVITIES

Recipients may not undertake promotional efforts (including activities of school officials, counselors, and vocational staff) in a manner that creates or perpetuates stereotypes or limitations based on race, color, national origin, sex or handicap. Examples of promotional efforts are career days, parents' night, shop demonstrations, visitations by groups of prospective students and by representatives from business and industry. Materials that are part of promotional efforts may not create or perpetuate stereotypes through text or illustration. To the extent possible they should portray males or females, minorities or handicapped persons in programs and occupations in which these groups traditionally have not been represented. If a recipient's service area contains a community of national origin minority persons with limited English language skills, promotional literature must be distributed to that community in its language.

VI. EQUAL OPPORTUNITY IN THE VOCATIONAL EDUCATION INSTRUCTIONAL SETTING

A. ACCOMMODATIONS FOR HANDICAPPED STUDENTS

Recipients must place secondary level handicapped students in the regular educational environment of any vocational education program to the maximum extent appropriate to the needs of the student unless it can be demonstrated that the education of the handicapped person in the regular environment with the use of supplementary aids and services cannot be achieved satisfactorily. Handicapped students may be placed in a program only after the recipient satisfies the provisions of the Department's Regulation, 45 CFR Part 84, relating to evaluation, placement, and procedural safeguards. If a separate class or facility is identifiable as being for handicapped persons, the facility, the programs, and the services must be comparable to the facilities, programs, and services offered to nonhandicapped students.

B. STUDENT FINANCIAL ASSISTANCE

Recipients may not award financial assistance in the form of loans, grants, scholarships, special funds, subsidies, compensation for work, or prizes to vocational education students on the basis of race, color, national origin, sex, or handicap, except to overcome the effects of past discrimination. Recipients may administer sex restricted financial assistance where the assistance and restriction are established by will, trust, bequest, or any similar legal instrument, if the overall effect of all financial assistance awarded does not discriminate on the basis of sex. Materials and information used to notify students of opportunities for financial assistance may not contain language or examples that would lead applicants to believe the assistance is provided on a discriminatory basis. If a recipient's service area contains a community of national origin minority persons with limited English language skills, such information must be disseminated to that community in its language.

C. HOUSING IN RESIDENTIAL POSTSECONDARY VOCATIONAL EDUCATION CENTERS

Recipients must extend housing opportunities without discrimination based on race, color, national origin, sex, or handicap. This obligation extends to recipients that provide on-campus housing and/or that have agreements with providers of off-campus housing. In particular, a recipient postsecondary vocational education program that provides on-campus or off-campus housing to its nonhandicapped students must provide, at the same cost and under the same conditions, comparable convenient and accessible housing to handicapped students.

D. COMPARABLE FACILITIES

Recipients must provide changing rooms, showers, and other facilities for students of one sex that are comparable to those provided to students of the other sex. This may be accomplished by alternating use of the same facilities or by providing separate, comparable facilities.

Such facilities must be adapted or modified to the extent necessary to make the vocational education program readily accessible to handicapped persons.

VII. WORK STUDY, COOPERATIVE VOCATIONAL EDUCATION, JOB PLACEMENT, AND APPRENTICE TRAINING

A. RESPONSIBILITIES IN COOPERATIVE VOCATIONAL EDUCATION PROGRAMS, WORK-STUDY PROGRAMS, AND JOB PLACEMENT PROGRAMS

A recipient must insure that: (a) It does not discriminate against its students on the basis of race, color, national origin, sex, or handicap in making available opportunities in cooperative education, work study and job placement programs; and (b) students participating in cooperative education, work study and job placement programs are not discriminated against by employers or prospective employers on the basis of race, color, national origin, sex, or handicap in recruitment, hiring, placement, assignment to work tasks, hours of employment, levels of responsibility, and in pay.

If a recipient enters into a written agreement for the referral or assignment of students to an employer, the agreement must contain an assurance from the employer that students will be accepted and assigned to jobs and otherwise treated without regard to race, color, national origin, sex, or handicap.

Recipients may not honor any employer's request for students who are free of handicaps or for students of a particular race, color, national origin, or sex. In the event an employer or prospective employer is or has been subject to court action involving discrimination in employment, school officials should rely on the court's findings if the decision resolves the issue of whether the employer has engaged in unlawful discrimination.

B. APPRENTICE TRAINING PROGRAMS

A recipient may not enter into any agreement for the provision or support of apprentice training for students or union members with any labor union or other sponsor that discriminates against its members or applicants for membership on the basis of race, color, national origin, sex, or handicap. If a recipient enters into a written agreement with a labor union or other sponsor providing for apprentice training, the agreement must contain an assurance from the union or other sponsor: (1) That it does not engage in such discrimination against its membership or applicants for membership; and (2) that apprentice training will be offered and conducted for its membership free of such discrimination.

VIII. EMPLOYMENT OF FACULTY AND STAFF

A. EMPLOYMENT GENERALLY

Recipients may not engage in any employment practice that discriminates against any employee or applicant for employment on the basis of sex or handicap. Recipients may not engage in any employment practice that discriminates on the basis of race, color, or national origin if such discrimination tends to result in segregation, exclusion or other discrimination against students.

B. RECRUITMENT

Recipients may not limit their recruitment for employees to schools, communities, or companies disproportionately composed of persons of a particular race, color, national origin, sex, or handicap except for the purpose of overcoming the effects of past discrimination. Every source of faculty must be notified that the recipient does not discriminate in employment on the basis of race, color, national origin, sex, or handicap.

C. PATTERNS OF DISCRIMINATION

Whenever the Office for Civil Rights finds that in light of the representation of protected groups in the relevant labor market there is a significant underrepresentation or overrepresentation of protected group persons on the staff of a vocational education school or program, it will presume that the disproportion results from unlawful discrimination. This presumption can be overcome by proof that qualified persons of the particular race, color, national origin, or sex, or that qualified handicapped persons are not in fact available in the relevant labor market.

D. SALARY POLICIES

Recipients must establish and maintain faculty salary scales and policy based upon the conditions and responsibilities of employment, without regard to race, color, national origin, sex or handicap.

E. EMPLOYMENT OPPORTUNITIES FOR HANDICAPPED APPLICANTS

Recipients must provide equal employment opportunities for teaching and administrative positions to handicapped applicants who can perform the essential functions of the position in question. Recipients must make reasonable accommodation for the physical or mental limitations of handicapped applicants who are otherwise qualified unless recipients can demonstrate that the accommodation would impose an undue hardship.

F. THE EFFECTS OF PAST DISCRIMINATION

Recipients must take steps to overcome the effects of past discrimination in the recruitment, hiring, and assignment of faculty. Such steps may include the recruitment or reassignment of qualified persons of a particular race, national origin, or sex, or who are handicapped.

G. STAFF OF STATE ADVISORY COUNCILS OF VOCATIONAL EDUCATION

State Advisory Councils of Vocational Education are recipients of Federal financial assistance and therefore must comply with Section VIII of the Guidelines.

H. EMPLOYMENT AT STATE OPERATED VOCATIONAL EDUCATION CENTERS THROUGH STATE CIVIL-SERVICE AUTHORITIES

Where recruitment and hiring of staff for State operated vocational education centers is conducted by a State civil service employment authority, the State education agency operating the program must insure that recruitment and hiring of staff for the vocational education center is conducted in accordance with the requirements of these Guidelines.

IX. PROPRIETARY VOCATIONAL EDUCATION SCHOOLS

A. RECIPIENT RESPONSIBILITIES

Proprietary vocational education schools that are recipients of Federal financial assistance through Federal student assistance programs or otherwise are subject to all of the requirements of the Department's regulations and these Guidelines.

B. ENFORCEMENT AUTHORITY

Enforcement of the provisions of Title IX of the Education Amendments of 1972 and section 504 of the Rehabilitation Act of 1973 is the responsibility of the Department of Health and Human Services. However, authority to enforce Title VI of the Civil rights Act of 1964 for proprietary vocational education schools has been delegated to the Veterans Administration.

When the Office for Civil Rights receives a Title VI complaint alleging discrimination by a proprietary vocational education school it will forward the complaint to the Veterans Administration and cite the applicable requirements of the Department's regulations and these Guidelines. The complainant will be notified of such action.

[44 FR 17164, Mar. 21, 1979]

PART 81—PRACTICE AND PROCEDURE FOR HEARINGS UNDER PART 80 OF THIS TITLE

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AUTHORITY: 5 U.S.C. 301 and 45 CFR 80.9(d).

SOURCE: 32 FR 15156, Nov. 2, 1967, unless otherwise noted.

Subpart A—General Information

§ 81.1 Scope of rules.

The rules of procedure in this part supplement §§ 80.9 and 80.10 of this subtitle and govern the practice for hearings, decisions, and administrative review conducted by the Department of Health and Human Services, pursuant to Title VI of the Civil Rights Act of 1964 (section 602, 78 Stat. 252) and Part 80 of this subtitle.

§ 81.2 Records to be public.

All pleadings, correspondence, exhibits, transcripts, of testimony, exceptions, briefs, decisions, and other documents filed in the docket in any proceeding may be inspected and copied in the office of the Civil Rights hearing clerk. Inquiries may be made at the Central Information Center, Department of Health and Human Services, 330 Independence Avenue SW., Washington, DC 20201.

§ 81.3 Use of gender and number.

As used in this part, words importing the singular number may extend and be applied to several persons or things, and vice versa. Words importing the masculine gender may be applied to females or organizations.

§ 81.4 Suspension of rules.

Upon notice to all parties, the reviewing authority or the presiding officer, with respect to matters pending before them, may modify or waive any rule in this part upon determination that no party will be unduly prejudiced and the ends of justice will thereby be served.

Subpart B—Appearance and Practice

§ 81.11 Appearance.

A party may appear in person or by counsel and participate fully in any proceeding. A State agency or a corporation may appear by any of its officers or by any employee it authorizes to appear on its behalf. Counsel must be members in good standing of the bar of a State, Territory, or possession of the United States or of the District of Columbia or the Commonwealth of Puerto Rico.

§ 81.12 Authority for representation.

Any individual acting in a representative capacity in any proceeding may be required to show his authority to act in such capacity.

§ 81.13 Exclusion from hearing for misconduct.

Disrespectful, disorderly, or contumacious language or contemptuous conduct, refusal to comply with directions, or continued use of dilatory tactics by any person at any hearing before a presiding officer shall constitute grounds for immediate exclusion of such person from the hearing by the presiding officer.

Subpart C—Parties

§ 81.21 Parties; General Counsel deemed a party.

(a) The term party shall include an applicant or recipient or other person to whom a notice of hearing or opportunity for hearing has been mailed naming him a respondent.

(b) The General Counsel of the Department of Health and Human Services shall be deemed a party to all proceedings.

§ 81.22 Amici curiae.

(a) Any interested person or organization may file a petition to participate in a proceeding as an amicus curiae. Such petition shall be filed prior to the prehearing conference, or if none is held, before the commencement of the hearing, unless the petitioner shows good cause for filing the petition later. The presiding officer may grant the petition if he finds that the petitioner has a legitimate interest in the proceedings, that such participation will not unduly delay the outcome, and may contribute materially to the proper disposition thereof. An amicus curiae is not a party and may not introduce evidence at a hearing.

(b) An amicus curiae may submit a statement of position to the presiding officer prior to the beginning of a hearing, and shall serve a copy on each party. The amicus curiae may submit a brief on each occasion a decision is to be made or a prior decision is subject to review. His brief shall be filed and served on each party within the time limits applicable to the party whose position he deems himself to support; or if he does not deem himself to support the position of any party, within the longest time limit applicable to any party at that particular stage of the proceedings.

(c) When all parties have completed their initial examination of a witness, any amicus curiae may request the presiding officer to propound specific questions to the witness. The presiding officer, in his discretion, may grant any such request if he believes the proposed additional testimony may assist materially in elucidating factual matters at issue between the parties and will not expand the issues.

§ 81.23 Complainants not parties.

A person submitting a complaint pursuant to § 80.7(b) of this title is not a party to the proceedings governed by this part, but may petition, after proceedings are initiated, to become an amicus curiae.

Subpart D—Form, Execution, Service and Filing of Documents

§ 81.31 Form of documents to be filed.

Documents to be filed under the rules in this part shall be dated, the original signed in ink, shall show the docket description and title of the proceeding, and shall show the title, if any, and address of the signatory. Copies need not be signed but the name of the person signing the original shall be reproduced. Documents shall be legible and shall not be more than 8½ inches wide and 12 inches long.

§ 81.32 Signature of documents.

The signature of a party, authorized officer, employee or attorney constitutes a certificate that he has read the document, that to the best of his knowledge, information, and belief there is good ground to support it, and that it is not interposed for delay. If a document is not signed or is signed with intent to defeat the purpose of this section, it may be stricken as sham and false and the proceeding may proceed as though the document had not been filed. Similar action may be taken if scandalous or indecent matter is inserted.

§ 81.33 Filing and service.

All notices by a Department official, and all written motions, requests, petitions, memoranda, pleadings, exceptions, briefs, decisions, and correspondence to a Department official from a party, or vice versa, relating to a proceeding after its commencement shall be filed and served on all parties. Parties shall supply the original and two copies of documents submitted for filing. Filings shall be made with the Civil Rights hearing clerk at the address stated in the notice of hearing or notice of opportunity for hearing, during regular business hours. Regular business hours are every Monday through Friday (legal holidays in the District of Columbia excepted) from 9 a.m. to 5:30 p.m., eastern standard or daylight saving time, whichever is effective in the District of Columbia at the time. Originals only on exhibits and transcripts of testimony need be filed. For requirements of service on amici curiae, see § 81.107.

§ 81.34 Service—how made.

Service shall be made by personal delivery of one copy to each person to be served or by mailing by first-class mail, properly addressed with postage prepaid. When a party or amicus has appeared by attorney or other representative, service upon such attorney or representative will be deemed service upon the party or amicus. Documents served by mail preferably should be mailed in sufficient time to reach the addressee by the date on which the original is due to be filed, and should be air mailed if the addressee is more than 300 miles distant.

§ 81.35 Date of service.

The date of service shall be the day when the matter is deposited in the U.S. mail or is delivered in person, except that the date of service of the initial notice of hearing or opportunity for hearing shall be the date of its delivery, or of its attempted delivery if refused.

§ 81.36 Certificate of service.

The original of every document filed and required to be served upon parties to a proceeding shall be endorsed with a certificate of service signed by the party making service or by his attorney or representative, stating that such service has been made, the date of service, and the manner of service, whether by mail or personal delivery.

Subpart E—Time

§ 81.41 Computation.

In computing any period of time under the rules in this part or in an order issued hereunder, the time begins with the day following the act, event, or default, and includes the last day of the period, unless it is a Saturday, Sunday, or legal holiday observed in the District of Columbia, in which event it includes the next following business day. When the period of time prescribed or allowed is less than 7 days, intermediate Saturdays, Sundays, and legal holidays shall be excluded from the computation.

§ 81.42 Extension of time or postponement.

Requests for extension of time should be served on all parties and should set forth the reasons for the application. Applications may be granted upon a showing of good cause by the applicant. From the designation of a presiding officer until the issuance of his decision such requests should be addressed to him. Answers to such requests are permitted, if made promptly.

§ 81.43 Reduction of time to file documents.

For good cause, the reviewing authority or the presiding officer, with respect to matters pending before them, may reduce any time limit prescribed by the rules in this part, except as provided by law or in Part 80 of this title.

Subpart F—Proceedings Prior to Hearing

§ 81.51 Notice of hearing or opportunity for hearing.

Proceedings are commenced by mailing a notice of hearing or opportunity for hearing to an affected applicant or recipient, pursuant to § 80.9 of this title.

§ 81.52 Answer to notice.

The respondent, applicant or recipient may file an answer to the notice within 20 days after service thereof. Answers shall admit or deny specifically and in detail each allegation of the notice, unless the respondent party is without knowledge, in which case his answer should so state, and the statement will be deemed a denial. Allegations of fact in the notice not denied or controverted by answer shall be deemed admitted. Matters alleged as affirmative defenses shall be separately stated and numbered. Failure of the respondent to file an answer within the 20-day period following service of the notice may be deemed an admission of all matters of fact recited in the notice.

§ 81.53 Amendment of notice or answer.

The General Counsel may amend the notice of hearing or opportunity for hearing once as a matter of course before an answer thereto is served, and each respondent may amend his answer once as a matter of course not later than 10 days before the date fixed for hearing but in no event later than 20 days from the date of service of his original answer. Otherwise a notice or answer may be amended only by leave of the presiding officer. A respondent shall file his answer to an amended notice within the time remaining for filing the answer to the original notice or within 10 days after service of the amended notice, whichever period may be the longer, unless the presiding officer otherwise orders.

§ 81.54 Request for hearing.

Within 20 days after service of a notice of opportunity for hearing which does not fix a date for hearing the respondent, either in his answer or in a separate document, may request a hearing. Failure of the respondent to request a hearing shall be deemed a waiver of the right to a hearing and to constitute his consent to the making of a decision on the basis of such information as is available.

§ 81.55 Consolidation.

The responsible Department official may provide for proceedings in the Department to be joined or consolidated for hearing with proceedings in other Federal departments or agencies, by agreement with such other departments or agencies. All parties to any proceeding consolidated subsequently to service of the notice of hearing or opportunity for hearing shall be promptly served with notice of such consolidation.

§ 81.56 Motions.

Motions and petitions shall state the relief sought, the authority relied upon, and the facts alleged. If made before or after the hearing, these matters shall be in writing. If made at the hearing, they may be stated orally; but the presiding officer may require that they be reduced to writing and filed and served on all parties in the same manner as a formal motion. Motions, answers, and replies shall be addressed to the presiding officer, if the case is pending before him. A repetitious motion will not be entertained.

§ 81.57 Responses to motions and petitions.

Within 8 days after a written motion or petition is served, or such other period as the reviewing authority or the presiding officer may fix, any party may file a response thereto. An immediate oral response may be made to an oral motion.

§ 81.58 Disposition of motions and petitions.

The reviewing authority or the presiding officer may not sustain or grant a written motion or petition prior to expiration of the time for filing responses thereto, but may overrule or deny such motion or petition without awaiting response: *Provided, however,* That prehearing conferences, hearings and decisions need not be delayed pending disposition of motions or petitions. Oral motions and petitions may be ruled on immediately. Motions and petitions submitted to the reviewing authority or the presiding officer, respectively, and not disposed of in separate rulings or in their respective decisions will be deemed denied. Oral arguments shall not be held or written motions or petitions unless the presiding officer in his discretion expressly so orders.

Subpart G—Responsibilities and Duties of Presiding Officer

§ 81.61 Who presides.

A hearing examiner assigned under 5 U.S.C. 3105 or 3344 (formerly section 11 of the Administrative Procedure Act) shall preside over the taking of evidence in any hearing to which these rules of procedure apply.

§ 81.62 Designation of hearing examiner.

The designation of the hearing examiner as presiding officer shall be in writing, and shall specify whether the examiner is to make an initial decision or to certify the entire record including his recommended findings and proposed decision to the reviewing authority, and may also fix the time and place of hearing. A copy of such order shall be served on all parties. After service of an order designating a hearing examiner to preside, and until such examiner makes his decision, motions and petitions shall be submitted to him. In the case of the death, illness, disqualification or unavailability of the designated hearing examiner, another hearing examiner may be designated to take his place.

§ 81.63 Authority of presiding officer.

The presiding officer shall have the duty to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order. He shall have all powers necessary to these ends, including (but not limited to) the power to:

(a) Arrange and issue notice of the date, time, and place of hearings, or, upon due notice to the parties, to change the date, time, and place of hearings previously set.

(b) Hold conferences to settle, simplify, or fix the issues in a proceeding, or to consider other matters that may aid in the expeditious disposition of the proceeding.

(c) Require parties and amici curiae to state their position with respect to the various issues in the proceeding.

(d) Administer oaths and affirmations.

(e) Rule on motions, and other procedural items on matters pending before him.

(f) Regulate the course of the hearing and conduct of counsel therein.

(g) Examine witnesses and direct witnesses to testify.

(h) Receive, rule on, exclude or limit evidence.

(i) Fix the time for filing motions, petitions, briefs, or other items in matters pending before him.

(j) Issue initial or recommended decisions.

(k) Take any action authorized by the rules in this part or in conformance with the provisions of 5 U.S.C. 551-559 (the Administrative Procedure Act).

Subpart H—Hearing Procedures

§ 81.71 Statement of position and trial briefs.

The presiding officer may require parties and amici curiae to file written statements of position prior to the beginning of a hearing. The presiding officer may also require the parties to submit trial briefs.

§ 81.72 Evidentiary purpose.

(a) The hearing is directed to receiving factual evidence and expert opinion testimony related to the issues in the proceeding. Argument will not be received in evidence; rather it should be presented in statements, memoranda, or briefs, as determined by the presiding officer. Brief opening statements, which shall be limited to statement of the party's position and what he intends to prove, may be made at hearings.

(b) Hearings for the reception of evidence will be held only in cases where issues of fact must be resolved in order to determine whether the respondent has failed to comply with one or more applicable requirements of Part 80 of this title. In any case where it appears from the respondent's answer to the notice of hearing or opportunity for hearing, from his failure timely to answer, or from his admissions or stipulations in the record, that there are no matters of material fact in dispute, the reviewing authority or presiding officer may enter an order so finding, vacating the hearing date if one has been set, and fixing the time for filing briefs under § 81.101. Thereafter the proceedings shall go to conclusion in accordance with Subpart J of this part. The presiding officer may allow an appeal from such order in accordance with § 81.86.

§ 81.73 Testimony.

Testimony shall be given orally under oath or affirmation by witnesses at the hearing; but the presiding officer, in his discretion, may require or permit that the direct testimony of any witness be prepared in writing and served on all parties in advance of the hearing. Such testimony may be adopted by the witness at the hearing, and filed as part of the record thereof. Unless authorized by the presiding officer, witnesses will not be permitted to read prepared testimony into the record. Except as provided in §§ 81.75 and 81.76, witnesses shall be available at the hearing for cross-examination.

§ 81.74 Exhibits.

Proposed exhibits shall be exchanged at the prehearing conference, or otherwise prior to the hearing if the presiding officer so requires. Proposed exhibits not so exchanged may be denied admission as evidence. The authenticity of all proposed exhibits exchanged prior to hearing will be deemed admitted unless written objection thereto is filed prior to the hearing or unless good cause is shown at the hearing for failure to file such written objection.

§ 81.75 Affidavits.

An affidavit is; not inadmissible as such. Unless the presiding officer fixes other time periods affidavits shall be filed and served on the parties not later than 15 days prior to the hearing; and not less than 7 days prior to hearing a party may file and serve written objection to any affidavit on the ground that he believes it necessary to test the truth of assertions therein at hearing. In such event the assertions objected to will not be received in evidence unless the affiant is made available for cross-examination, or the presiding officer determines that cross-examination is not necessary for the full and true disclosure of facts referred to in such assertions. Notwithstanding any objection, however, affidavits may be considered in the case of any respondent who waives a hearing.

§ 81.76 Depositions.

Upon such terms as may be just, for the convenience of the parties or of the Department, the presiding officer may authorize or direct the testimony of any witness to be taken by deposition.

§ 81.77 Admissions as to facts and documents.

Not later than 15 days prior to the scheduled date of the hearing except for good cause shown, or prior to such earlier date as the presiding officer may order, any party may serve upon an opposing party a written request for the admission of the genuineness and authenticity of any relevant documents described in and exhibited with the request, or for the admission of the truth of any relevant matters of fact stated in the request. Each of the matters of which an admission is requested shall be deemed admitted, unless within a period designated in the request (not less than 10 days after service thereof, or within such further time as the presiding officer or the reviewing authority if no presiding officer has yet been designated may allow upon motion and notice) the party to whom the request is directed serves upon the requesting party a sworn statement either denying specifically the matters of which an admission is requested or setting forth in detail the reasons why he cannot truthfully either admit or deny such matters. Copies of requests for admission and answers thereto shall be served on all parties. Any admission made by a party to such request is only for the purposes of the pending proceeding, or any proceeding or action instituted for the enforcement of any order entered therein, and shall not constitute and admission by him for any other purpose or be used against him in any other proceeding or action.

§ 81.78 Evidence.

Irrelevant, immaterial, unreliable, and unduly repetitious evidence will be excluded.

§ 81.79 Cross-examination.

A witness may be cross-examined on any matter material to the proceeding without regard to the scope of his direct examination.

§ 81.80 Unsponsored written material.

Letters expressing views or urging action and other unsponsored written material regarding matters in issue in a hearing will be placed in the correspondence section of the docket of the proceeding. These data are not deemed part of the evidence or record in the hearing.

§ 81.81 Objections.

Objections to evidence shall be timely and briefly state the ground relied upon.

§ 81.82 Exceptions to rulings of presiding officer unnecessary.

Exceptions to rulings of the presiding officer are unnecessary. It is sufficient that a party, at the time the ruling of the presiding officer is sought, makes known the action which he desires the presiding officer to take, or his objection to an action taken, and his grounds therefor.

§ 81.83 Official notice.

Where official notice is taken or is to be taken of a material fact not appearing in the evidence of record, any party, on timely request, shall be afforded an opportunity to show the contrary.

§ 81.84 Public document items.

Whenever there is offered (in whole or in part) a public document, such as an official report, decision, opinion, or published scientific or economic statistical data issued by any of the executive departments (or their subdivisions), legislative agencies or committees, or administrative agencies of the Federal Government (including Government-owned corporations), or a similar document issued by a State or its agencies, and such document (or part thereof) has been shown by the offeror to be reasonably available to the public, such document need not be produced or marked for identification, but may be offered for official notice, as a public document item by specifying the document or relevant part thereof.

§ 81.85 Offer of proof.

An offer of proof made in connection with an objection taken to any ruling of the presiding officer rejecting or excluding proffered oral testimony shall consist of a statement of the substance of the evidence which counsel contends would be adduced by such testimony; and, if the excluded evidence consists of evidence in documentary or written form or of reference to documents or records, a copy of such evidence shall be marked for identification and shall accompany the record as the offer of proof.

§ 81.86 Appeals from ruling of presiding officer.

Rulings of the presiding officer may not be appealed to the reviewing authority prior to his consideration of the entire proceeding except with the consent of the presiding officer and where he certifies on the record or in writing that the allowance of an interlocutory appeal is clearly necessary to prevent exceptional delay, expense, or prejudice to any party, or substantial detriment to the public interest. If an appeal is allowed, any party may file a brief with the reviewing authority within such period as the presiding officer directs. No oral argument will be heard unless the reviewing authority directs otherwise. At any time prior to submission of the proceeding to it for decisions, the reviewing authority may direct the presiding officer to certify any question or the entire record to it for decision. Where the entire record is so certified, the presiding officer shall recommend a decision.

Subpart I—The Record

§ 81.91 Official transcript.

The Department will designate the official reporter for all hearings. The official transcripts of testimony taken, together with any exhibits, briefs, or memoranda of law filed therewith shall be filed with the Department. Transcripts of testimony in hearings may be obtained from the official reporter by the parties and the public at rates not to exceed the maximum rates fixed by the contract between the Department and the reporter. Upon notice to all parties, the presiding officer may authorize corrections to the transcript which involve matters of substance.

§ 81.92 Record for decision.

The transcript of testimony, exhibits, and all papers and requests filed in the proceedings, except the correspondence section of the docket, including rulings and any recommended or initial decision shall constitute the exclusive record for decision.

Subpart J—Posthearing Procedures, Decisions

§ 81.101 Posthearing briefs: proposed findings and conclusions.

(a) The presiding officer shall fix the time for filing posthearing briefs, which may contain proposed findings of fact and conclusions of law, and, if permitted, reply briefs.

(b) Briefs should include a summary of the evidence relied upon together with references to exhibit numbers and pages of the transcript, with citations of the authorities relied upon.

§ 81.102 Decisions following hearing.

When the time for submission of posthearing briefs has expired, the presiding officer shall certify the entire record, including his recommended findings and proposed decision, to the responsible Department official; or if so authorized he shall make an initial decision. A copy of the recommended findings and proposed decision, or of the initial decision, shall be served upon all parties, and amici, if any.

§ 81.103 Exceptions to initial or recommended decisions.

Within 20 days after the mailing of an initial or recommended decision, any party may file exceptions to the decision, stating reasons therefor, with the reviewing authority. Any other party may file a response thereto within 30 days after the mailing of the decision. Upon the filing of such exceptions, the reviewing authority shall review the decision and issue its own decision thereon.

§ 81.104 Final decisions.

(a) Where the hearing is conducted by a hearing examiner who makes an initial decision, if no exceptions thereto are filed within the 20-day period specified in § 81.103, such decision shall become the final decision of the Department, and shall constitute "final agency action" within the meaning of 5 U.S.C. 704 (formerly section 10(c) of the Administrative Procedure Act), subject to the provisions of § 81.106.

(b) Where the hearing is conducted by a hearing examiner who makes a recommended decision, or upon the filing of exceptions to a hearing examiner's initial decision, the reviewing authority shall review the recommended or initial decision and shall issue its own decision thereon, which shall become the final decision of the Department, and shall constitute "final agency action" within the meaning of 5 U.S.C. 704 (formerly section 10(c) of the Administrative Procedure Act), subject to the provisions of § 81.106.

(c) All final decisions shall be promptly served on all parties, and amici, if any.

§ 81.105 Oral argument to the reviewing authority.

(a) If any party desires to argue a case orally on exceptions or replies to exceptions to an initial or recommended decision, he shall make such request in writing. The reviewing authority may grant or deny such requests in its discretion. If granted, it will serve notice of oral argument on all parties. The notice will set forth the order of presentation, the amount of time allotted, and the time and place for argument. The names of persons who will argue should be filed with the Department hearing clerk not later than 7 days before the date set for oral argument.

(b) The purpose of oral argument is to emphasize and clarify the written argument in the briefs. Reading at length from the brief or other texts is not favored. Participants should confine their arguments to points of controlling importance and to points upon which exceptions have been filed. Consolidations of appearances at oral argument by parties taking the same side will permit the parties' interests to be presented more effectively in the time allotted.

(c) Pamphlets, charts, and other written material may be presented at oral argument only if such material is limited to facts already in the record and is served on all parties and filed with the Department hearing clerk at least 7 days before the argument.

§ 81.106 Review by the Secretary.

Within 20 days after an initial decision becomes a final decision pursuant to § 81.104(a) or within 20 days of the mailing of a final decision referred to in § 81.104(b), as the case may be, a party may request the Secretary to review the final decision. The Secretary may grant or deny such request, in whole or in part, or serve notice of his intent to review the decision in whole or in part upon his own motion. If the Secretary grants the requested review, or if he serves notice of intent to review upon his own motion, each party to the decision shall have 20 days following notice of the Secretary's proposed action within which to file exceptions to the decision and supporting briefs and memoranda, or briefs and memoranda in support of the decision. Failure of a party to request review under this paragraph shall not be deemed a failure to exhaust administrative remedies for the purpose of obtaining judicial review.

§ 81.107 Service on amici curiae.

All briefs, exceptions, memoranda, requests, and decisions referred to in this Subpart J shall be served upon amici curiae at the same times and in the same manner required for service on parties. Any written statements of position and trial briefs required of parties under § 81.71 shall be served on amici.

Subpart K—Judicial Standards of Practice

§ 81.111 Conduct.

Parties and their representatives are expected to conduct themselves with honor and dignity and observe judicial standards of practice and ethics in all proceedings. They should not indulge in offensive personalities, unseemly wrangling, or intemperate accusations or characterizations. A representative of any party whether or not a lawyer shall observe the traditional responsibilities of lawyers as officers of the court and use his best efforts to restrain his client from improprieties in connection with a proceeding.

§ 81.112 Improper conduct.

With respect to any proceeding it is improper for any interested person to attempt to sway the judgement of the reviewing authority by undertaking to bring pressure or influence to bear upon any officer having a responsibility for a decision in the proceeding, or his decisional staff. It is improper that such interested persons or any members of the Department's staff or the presiding officer give statements to communications media, by paid advertisement or otherwise, designed to influence the judgement of any officer having a responsibility for a decision in the proceeding, or his decisional staff. It is improper for any person to solicit communications to any such officer, or his decisional staff, other than proper communications by parties or amici curiae.

§ 81.113 Ex Parte communications.

Only persons employed by or assigned to work with the reviewing authority who perform no investigative or prosecuting function in connection with a proceeding shall communicate ex parte with the reviewing authority, or the presiding officer, or any employee or person involved in the decisional process in such proceedings with respect to the merits of that or a factually related proceeding. The reviewing authority, the presiding officer, or any employee or person involved in the decisional process of a proceeding shall communicate ex parte with respect to the merits of that or a factually related proceeding only with persons employed by or assigned to work with them and who perform no investigative or prosecuting function in connection with the proceeding.

§ 81.114 Expeditious treatment.

Requests for expeditious treatment of matters pending before the responsible Department official or the presiding officer are deemed communications on the merits, and are improper except when forwarded from parties to a proceeding and served upon all other parties thereto. Such communications should be in the form of a motion.

§ 81.115 Matters not prohibited.

A request for information which merely inquires about the status of a proceeding without discussing issues or expressing points of view is not deemed an ex parte communication. Such requests should be directed to the Civil Rights hearing clerk. Communications with respect to minor procedural matters or inquiries or emergency requests for extensions of time are not deemed ex parte communications prohibited by § 81.113. Where feasible, however, such communications should be by letter with copies to all parties. Ex parte communications between a respondent and the responsible Department official or the Secretary with respect to securing such respondent's voluntary compliance with any requirement of Part 80 of this title are not prohibited.

§ 81.116 Filing of ex parte communications.

A prohibited communication in writing received by the Secretary, the reviewing authority, or by the presiding officer, shall be made public by placing it in the correspondence file of the docket in the case and will not be considered as part of the record for decision. If the prohibited communication is received orally a memorandum setting forth its substance shall be made and filed in the correspondence section of the docket in the case. A person referred to in such memorandum may file a comment for inclusion in the docket if he considers the memorandum to be incorrect.

Subpart L—Posttermination Proceedings

§ 81.121 Posttermination proceedings.

(a) An applicant or recipient adversely affected by the order terminating, discontinuing, or refusing Federal financial assistance in consequence of proceedings pursuant to this title may request the responsible Department official for an order authorizing payment, or permitting resumption, of Federal financial assistance. Such request shall be in writing and shall affirmatively show that since entry of the order, it has brought its program or activity into compliance with the requirements of the Act, and with the Regulation thereunder, and shall set forth specifically, and in detail, the steps which it has taken to achieve such compliance. If the responsible Department official denies such request the applicant or recipient shall be given an expeditious hearing if it so requests in writing and specifies why it believes the responsible Department official to have been in error. The request for such a hearing shall be addressed to the responsible Department official and shall be made within 30 days after the applicant or recipient is informed that the responsible Department official has refused to authorize payment or permit resumption of Federal financial assistance.

(b) In the event that a hearing shall be requested pursuant to paragraph (a) of this section, the hearing procedures established by this part shall be applicable to the proceedings, except as otherwise provided in this section.

Subpart M—Definitions

§ 81.131 Definitions.

The definitions contained in § 80.13 of this subtitle apply to this part, unless the context otherwise requires, and the term "reviewing authority" as used herein includes the Secretary of Health and Human Services, with respect to action by that official under § 81.106.

Transition provisions: (a) The amendments herein shall become effective upon publication in the FEDERAL REGISTER.

(b) These rules shall apply to any proceeding or part thereof to which Part 80 of this title as amended effective October 19, 1967 (published in the FEDERAL REGISTER for October 19, 1967), and as the same may be hereafter amended, applies. In the case of any proceeding or part thereof governed by the provisions of Part 80 as that part existed prior to such amendment, and rules in this Part 81 shall apply as if these amendments were not in effect.

PART 83—REGULATION FOR THE ADMINISTRATION AND ENFORCEMENT OF SECTIONS 799A AND 845 OF THE PUBLIC HEALTH SERVICE ACT

Subpart A—Purposes; Definitions; Coverage

Sec.
83.1 Purposes.
83.2 Definitions.
83.3 Remedial and affirmative actions.
83.4 Coverage.
83.5 Effect of title IX of the Education Amendments of 1972.
83.6—83.9 [Reserved]

Subpart B—Discrimination in Admissions Prohibited

83.10 General obligations.
83.11 Discriminatory acts prohibited.
83.12 Recruitment.
83.13 State law and licensure requirements.
83.14 Development and dissemination of nondiscrimination policy.
83.15 Designation by entity of responsible employee and adoption of grievance procedures.
83.16—83.19 [Reserved]

Subpart C—Procedures [Interim]

83.20 Interim procedures.

AUTHORITY: Sec. 215(b), Public Health Service Act (42 U.S.C. 216(b)).

SOURCE: 40 FR 28573, July 7, 1975, unless otherwise noted.

Subpart A—Purposes; Definitions; Coverage

§ 83.1 Purposes.

(a) The purposes of this part are (1) to effectuate the provisions of sections 799A and 845 of the Public Health Service Act, which forbid the extension of Federal support under title VII or VIII of that Act to any entity of the types described in those sections unless that entity submits to the Secretary of Health and Human Services an assurance satisfactory to the Secretary that it will not discriminate on the basis of sex in the admission of individuals to its training programs, and (2) to implement the policy of the Secretary that no Federal support will be extended under those titles to any other entity unless that entity submits to the Secretary an assurance satisfactory to the Secretary that it will not discriminate on the basis of sex in the admission of individuals to its training programs.

(b) The objective of this part is to abolish use of sex as a criterion in the admission of individuals to all training programs operated by an entity which receives support under title VII or VIII of the Act, and thereby to foster maximum use of all available human resources in meeting the Nation's needs for qualified health personnel.

§ 83.2 Definitions.

As used in this part the term—

(a) "Act" means the Public Health Service Act.

(b) "Administrative law judge" means a person appointed by the Reviewing Authority to preside over a hearing held under this part.

(c) "Assurance commitment clause" means a clause in an invitation for a contract offer extended by the Federal Government under title VII or VIII of the Act which, when executed by an entity as part of such offer, becomes, upon acceptance of such offer by the Federal Government, a contractual obligation of such entity to comply with its assurance submitted to the Director under this part.

(d) "Department" means the Department of Health and Human Services.

(e) "Director" means the Director of the Office for Civil Rights of the Department.

(f) "Entity" means (1) a school of medicine, school of dentistry, school of osteopathy, school of pharmacy, school of optometry, school of podiatry, school of veterinary medicine, or school of public health, as defined by section 724 of the Act;

(2) A school of nursing, as defined by section 843 of the Act;

(3) A school or college of a training center for an allied health profession, as defined by section 795 of the Act, or of another institution of undergraduate education which school or college can provide a training program;

(4) An affiliated hospital, as defined by section 724 or 795 of the Act; and

(5) Any other institution, organization, consortium, or agency which is eligible to receive Federal support.

(g) "Federal support" means assistance extended after November 18, 1971, under title VII or VIII of the Act to an entity by means of a grant to, a contract with, or a loan guarantee or interest subsidy payment made on behalf of, such entity.

(h) "Federally supported entity" means an entity which receives Federal support.

(i) "Reviewing authority" means that component of the Department to which the Secretary delegates authority to review the decision of an administrative law judge in a proceeding arising under this part.

(j) "Secretary" means the Secretary of Health and Human Services.

(k) "Training program" means a program of training described by section 724(4) of the Act, a program of education described by, or specified by regulations pursuant to, section 795(1) of the Act, a program of education described by section 843(c), 843(d), or 843(e) of the Act, and a program leading to any license or certification requisite to the practice of a health profession for which a degree specified in any such section is granted.

§ 83.3 Remedial and affirmative actions.

(a) *Remedial action.* If the Director finds that an entity has discriminated against persons on the basis of sex in any of its training programs, such entity shall take such remedial action as the Director deems necessary to overcome the effects of such discrimination.

(b) *Affirmative action.* In the absence of a finding of discrimination on the basis of sex in a training program, an entity may take affirmative action to overcome the effects of conditions which resulted in limited participation therein by persons of a particular sex.

§ 83.4 Coverage.

(a) If an entity receives Federal support for any of its training programs, all of its training programs thereby become subject to this part.

(b) The obligation imposed by this part on a federally supported entity not to discriminate on the basis of sex in the admission of individuals to a training program includes not only the obligation not to discriminate on such basis in the selection of individuals for such program, but also the obligation not to discriminate on such basis against individuals after their selection for such program.

(c) The obligation imposed by this part on a federally supported entity not to discriminate on the basis of sex against an individual who is an applicant for, or is enrolled in, a training program is applicable to the same extent to the actions of such entity with respect to an applicant for, or a student enrolled in, an undergraduate program of education of such entity if individuals enrolled in such program must complete all or a part of such programs to be eligible for admission to an undergraduate training program of such entity.

(d) An entity shall not discriminate on the basis of sex in violation of this part for as long as such entity receives or benefits from Federal support. For purposes of the preceding sentence, an entity shall be deemed to continue to receive or benefit from Federal support for as long as it retains ownership, possession, or use of either real or personal property and which was acquired in whole or in part with Federal support. If an entity receives value for property which was acquired in whole or in part with Federal support and such value is applied toward the acquisition of other property, such entity shall be deemed to continue to receive or benefit from such support for as long as such entity retains ownership, use, or possession of such other property.

(e) An entity shall not transfer property which was acquired, constructed, altered, repaired, expanded, or renovated in whole or in part with Federal support unless the agency, organization, or individual to whom such property is to be transferred has submitted to the Director, and he or she has found satisfactory, an assurance of compliance with this part. The preceding sentence shall not apply with respect to any real or personal property for which payments have been recaptured by the United States under title VII or VIII of the Act, with respect to any other property for which the transferring entity has refunded to the Federal Government the Federal share of the fair market value of such property, or with respect to any personal property which has only scrap value to both the entity and the agency, organization or individual to which the property is to be transferred.

§ 83.5 Effect of title IX of the Education Amendments of 1972.

The obligations imposed by this part are independent of obligations imposed by or pursuant to title IX of the Education Amendments of 1972.

§§ 83.6—83.9 [Reserved]

Subpart B—Discrimination in Admissions Prohibited

§ 83.10 General obligations.

(a) *Eligibility for support.* No entity will be provided Federal support unless such entity has furnished the Director assurances satisfactory to him or her that it will not discriminate on the basis of sex, in violation of this part, in the admission of individuals to each of its training programs.

(b) *Eliminating the effects of discrimination.* An assurance of compliance with this part will not be satisfactory to the Director if the entity submitting such assurance fails to take whatever remedial action in accordance with § 83.3(a) that is necessary for such entity to eliminate the effects of any discrimination on the basis of sex in the admission of individuals to its training programs that such entity practiced prior to the submission to the Director of such assurance, or practices at the time of or subsequent to such submission. The Director may require such entity, as a condition to determining that its assurance is, or remains, satisfactory, to take specific actions, or to submit to him or her specific information, bearing upon compliance with this part.

§ 83.11 Discriminatory acts prohibited.

(a) *General.* No person shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any academic, extracurricular, research, occupational training, or other training program or activity operated by an entity.

(b) *Discrimination in selection.* In determining whether an individual satisfies any enrollment, eligibility, or other condition for selection for a training program, a federally supported entity shall not:

(1) On the basis of sex, given preference to one individual over another by ranking applicants on such basis, or otherwise give such preference; or

(2) Apply numerical limitations upon the number or proportion of persons of either sex who may be admitted; or

(3) Otherwise treat one individual differently from another on the basis of sex.

(c) *Testing.* A federally supported entity shall not administer or operate any test or use any criterion for admission which has a disproportionately adverse effect on persons on the basis of sex unless the use of such test or criterion is shown validly to predict success in the training program or activity in question and alternative tests or criteria which do not have such a disproportionately adverse effect are shown to be unavailable.

(d) *Prohibitions relating to marital or parental status.* In determining whether a person satisfies any policy or criterion for admission, or in making any offer of admission, in providing financial aid or any other benefit, an entity to which this subpart applies:

(1) Shall not apply any rule concerning the actual or potential parental, family, or marital status of a student or applicant which treats persons differently on the basis of sex;

(2) Shall not discriminate against or exclude any person on the basis of pregnancy, childbirth, termination of pregnancy or recovery therefrom, or establish or follow any rule or practice which so discriminates or excludes;

(3) Shall treat pregnancy, childbirth, termination of pregnancy and any temporary disabilities related to or resulting from pregnancy, childbirth, termination of pregnancy or recovery therefrom in the same manner and under the same policies as any other temporary disability or physical condition; and

(4) Shall not make pre-admission inquiry as to the marital status of an applicant for admission, including whether such applicant is "Miss," or "Mrs." A recipient may make pre-admission inquiry as to the sex of an applicant for admission, but only if such inquiry is made equally of such applicants of both sexes and if the results of such inquiry are not used in connection with discrimination prohibited by this part.

(e) *Preference to students from other institutions in admission.* An entity shall not give preference to applicants for admission, on the basis of attendance at any educational institution or other school or entity which admits as students only or predominantly members of one sex, if the giving of such preference has the effect of discriminating on the basis of sex in violation of this part.

(f) *Discrimination in the provision of benefits and services*—(1) *General.* Except as otherwise provided in this part in providing financial aid or any other benefit, or in providing any service, to an applicant for a training program or to a student enrolled in such program, no federally supported entity shall on the basis of sex:

(i) Treat one individual differently from another in determining whether such individual satisfies any requirement or condition for the provision of such benefit of service;

(ii) Provide a different benefit or service or provide a benefit or a service in a different manner;

(iii) Deny an individual any such benefit or service;

(iv) Subject an individual to separate treatment or rules of behavior;

(v) Discriminate against any individual by assisting an agency, organization, or individual in providing, in a manner which discriminates on the basis of sex, a benefit or service to applicants for or students enrolled in a training program; or

(vi) Otherwise limit any individual in the enjoyment of any right, privilege, advantage, or opportunity.

(2) *Financial aid established by certain legal instruments.* (i) A recipient may administer or assist in the administration of scholarships, fellowships, or other forms of financial assistance

established pursuant to domestic or foreign wills, trusts, bequests, or similar legal instruments or by acts of a foreign government which requires that awards be made to members of a particular sex specified therein: *Provided,* That the overall effect of the award of such sex-restricted scholarships, fellowships, and other forms of financial assistance does not discriminate on the basis of sex.

(ii) To ensure nondiscriminatory awards of assistance as required in paragraph (f) (2) (i) of this section, recipients shall develop and use procedures under which:

(A) Students are selected for award of financial assistance on the basis of non-discriminatory criteria and not on the basis of availability of funds restricted to members of a particular sex;

(B) An appropriate sex-restricted scholarship, fellowship, or other form of financial assistance is allocated to each student selected under paragraph (f) (2) (ii) (A) of this section; and

(C) No student is denied the award for which he or she was selected under paragraph (f)(2)(ii)(A) of this section because of the absence of a scholarship, fellowship, or other form of financial assistance designated for a member of that student's sex.

(g) *Housing.* (1) An entity shall not, on the basis of sex, apply different rules or regulations, impose different fees or requirements, or offer different services or benefits related to housing, except as provided in this subsection (including housing provided only to married students).

(2) An entity may provide separate housing on the basis of sex.

(3) Housing provided by an entity to students of one sex, when compared to that provided to students of the other sex, shall be as a whole: (i) Proportionate in quantity to the number of students of that sex applying for such housing; and (ii) comparable in quality and cost to the student.

(4) An entity shall not on the basis of sex, administer different policies or practices concerning occupancy by its students of housing other than that provided by such recipient.

(5) An entity which, through solicitation, listing, approval of housing, or otherwise, assists any agency, organization, or person in making housing available to any of its students, shall take reasonable action to ensure that such housing is provided to students of one sex, when compared to that provided to students of the other sex, is as a whole: (i) Proportionate in quantity and (ii) comparable in quality and cost to the student. An entity may render such assistance to any agency, organization, or person which provides all or part of such housing to students only of one sex.

(h) *Inter-institutional programs.* If a federally supported entity aids participation, by any applicant for or student enrolled in any of its training programs, in any program or activity of another organization or agency, such entity shall:

(1) Develop and implement a procedure to assure itself that such organization or agency takes no action with respect to such applicants or students which this part would prohibit such entity from taking; and

(2) Not aid such participation if such organization or agency takes such action.

(i) *Discrimination in employment prohibited.* A federally supported entity shall not discriminate on the basis of sex in employment practices relating to its professional and other staff who work directly with applicants for or students enrolled in any of its training programs. The provisions of this subpart apply to:

(1) Recruitment, advertising, and the process of application for employment;

(2) Hiring, upgrading, promotion, consideration for and award of tenure, demotion, transfer, layoff, termination, right of return from layoff, and rehiring;

(3) Rates of pay or any other form of compensation, and changes in compensation;

(4) Job assignments, classifications and structure, including position descriptions, lines of progression, and seniority lists;

(5) The terms of any collective bargaining agreement;

(6) Granting and return from leaves of absence, pregnancy leave, leave for persons of either sex to care for chil-

dren or dependents, or any other leave;

(7) Fringe benefits available by virtue of employment, whether or not administered by the recipient;

(8) Selection and financial support for training, including apprenticeship, professional meetings, conferences, and other related activities, selection for tuition assistance, selection for sabbaticals and leaves of absence to pursue training;

(9) Employer-sponsored activities, including social or recreational programs; and

(10) Any other term, condition, or privilege of employment.

§ 83.12 Recruitment.

(a) *Comparable recruitment.* A federally supported entity shall, with respect to each of its training programs, make comparable efforts to recruit members of each sex in the geographic area from which such entity attracts its students. A federally supported entity shall not recruit for any of its training programs exclusively or primarily at organizations or agencies which admit as members or students, or which provide a service for, only members of one sex unless such entity can demonstrate that such action is part of a recruitment program which does not have the effect of discriminating on the basis of sex in selection for a training program.

(b) *Recruitment practices.* A federally supported entity shall:

(1) Prominently include a statement of its policy of nondiscrimination on the basis of sex in each announcement, bulletin, catalogue, or application form which describes the training program of such entity or is used in connection with the recruitment of employees who will work directly with applicants for or students enrolled in a training program;

(2) Distribute without discrimination on the basis of sex any announcements, bulletins, catalogues, or other materials used in connection with the recruitment of students for a training program or employees who will work directly with applicants for such program or such students; and

(3) Apprise each of its recruitment representatives of its policy of nondiscrimination on the basis of sex, and require such representatives to adhere to such policy.

§ 83.13 State law and licensure requirements.

The obligation of an entity to comply with this part is not obviated or alleviated by any State or local law which would render an applicant for or student enrolled in a training program ineligible on the basis of sex for any license or certificate requisite to the practice of the health profession for which such applicant seeks, or student pursues, training.

§ 83.14 Development and dissemination of nondiscrimination policy.

(a) A federally supported entity shall develop a written policy statement of nondiscrimination on the basis of sex, in accordance with this part, and shall implement specific and continuing steps to publicize such statement to applicants for admission or employment, students, employees, and sources of referral of applicants for admission or employment.

(b) Each federally supported entity shall prominently include a statement of the policy described in paragraph (a) of this section in each announcement, bulletin, catalogue, and application form which it makes available to any person of a type described in paragraph (a) of this section, or which is otherwise used in connection with the recruitment of students or employees who work directly with students and applicants for admission.

(c) A federally supported entity shall not use or distribute a publication of the type described in this section which suggests, by text or illustration, that such recipient treats applicants, students, or employees differently on the basis of sex except as such treatment is permitted by this part.

§ 83.15 Designation by entity of responsible employee and adoption of grievance procedures.

(a) *Designation of responsible employee.* A federally supported entity shall designate at least one employee to coordinate its efforts to comply with and carry out its responsibilities under this part, including any investigation of any complaint communicated to such entity alleging its noncompliance with this part or alleging any action which would be prohibited by this part. The entity shall notify all of its students and employees who work directly with students and applicants for admission of the name, office address and telephone number of the employee or employees appointed pursuant to this paragraph.

(b) *Complaint procedure of entity.* A federally supported entity shall adopt and publish grievance procedures providing for prompt and equitable resolution of student and employee complaints alleging any action which would be prohibited by this part. Such procedures shall be in writing and available to all present and prospective students and employees.

§§ 83.16—83.19 [Reserved]

Subpart C—Procedures [Interim]

§ 83.20 Interim procedures.

For the purposes of implementing this part during the period between its effective date and the final issuance by the Department of a consolidated procedural regulation applicable to sections 704 and 845 of the Act and other civil rights authorities administered by the Department, the procedural provisions applicable to title VI of the Civil Rights Act of 1964 are hereby adopted and incorporated herein by reference. These procedures may be found at 45 CFR 80.6 through 80.11 and 45 CFR Part 81.

PART 84—NONDISCRIMINATION ON THE BASIS OF HANDICAP IN PROGRAMS AND ACTIVITIES RECEIVING OR BENEFITING FROM FEDERAL FINANCIAL ASSISTANCE

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APPENDIX A TO PART 84—ANALYSIS OF FINAL REGULATION

APPENDIX B TO PART 84—GUIDELINES FOR ELIMINATING DISCRIMINATION AND DENIAL OF SERVICES ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, SEX, AND HANDICAP IN VOCATIONAL EDUCATION PROGRAMS [NOTE]

APPENDIX C TO PART 84—GUIDELINES RELATING TO HEALTH CARE FOR HANDICAPPED INFANTS

AUTHORITY: Sec. 504, Rehabilitation Act of 1973, Pub. L. 93-112, 87 Stat. 394 (29 U.S.C. 794); sec. 111(a), Rehabilitation Act Amendments of 1974, Pub. L. 93-516, 88 Stat. 1619 (29 U.S.C. 706); sec. 606, Education of the Handicapped Act (20 U.S.C. 1405), as amended by Pub. L. 94-142, 89 Stat. 795; sec. 321, Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, 84 Stat. 182 (42 U.S.C. 4581), as amended; sec. 407, Drug Abuse Office and Treatment Act of 1972, 86 Stat. 78 (21 U.S.C. 1174), as amended.

SOURCE: 42 FR 22677, May 4, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 84.1 Purpose.

The purpose of this part is to effectuate section 504 of the Rehabilitation Act of 1973, which is designed to eliminate discrimination on the basis of handicap in any program or activity receiving Federal financial assistance.

§ 84.2 Application.

This part applies to each recipient of Federal financial assistance from the Department of Health and Human Services and to each program or activity that receives or benefits from such assistance.

§ 84.3 Definitions.

As used in this part, the term:

(a) "The Act" means the Rehabilitation Act of 1973, Pub. L. 93-112, as amended by the Rehabilitation Act Amendments of 1974, Pub. L. 93-516, 29 U.S.C. 794.

(b) "Section 504" means section 504 of the Act.

(c) "Education of the Handicapped Act" means that statute as amended by the Education for all Handicapped Children Act of 1975, Pub. L. 94-142, 20 U.S.C. 1401 et seq.

(d) "Department" means the Department of Health and Human Services.

(e) "Director" means the Director of the Office for Civil Rights of the Department.

(f) "Recipient" means any state or its political subdivision, any instrumentality of a state or its political subdivision, any public or private agency, institution, organization, or other entity, or any person to which Federal financial assistance is extended directly or through another recipient, including any successor, assignee, or transferee of a recipient, but excluding the ultimate beneficiary of the assistance.

(g) "Applicant for assistance" means one who submits an application, request, or plan required to be approved by a Department official or by a recipient as a condition to becoming a recipient.

(h) "Federal financial assistance" means any grant, loan, contract (other than a procurement contract or a contract of insurance or guaranty), or any other arrangement by which the Department provides or otherwise makes available assistance in the form of:

(1) Funds;

(2) Services of Federal personnel; or

(3) Real and personal property or any interest in or use of such property, including:

(i) Transfers or leases of such property for less than fair market value or for reduced consideration; and

(ii) Proceeds from a subsequent transfer or lease of such property if the Federal share of its fair market value is not returned to the Federal Government.

(i) "Facility" means all or any portion of buildings, structures, equipment, roads, walks, parking lots, or other real or personal property or interest in such property.

(j) "Handicapped person." (1) "Handicapped persons" means any person who (i) has a physical or mental impairment which substantially limits one or more major life activities, (ii) has a record of such an impairment, or (iii) is regarded as having such an impairment.

(2) As used in paragraph (j)(1) of this section, the phrase:

(i) "Physical or mental impairment" means (A) any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems: neurological; musculoskeletal; special sense organs; respiratory, including speech organs; cardiovascular; reproductive, digestive, genito-urinary; hemic and lymphatic; skin; and endocrine; or (B) any mental or psychological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities

(ii) "Major life activities" means functions such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working.

(iii) "Has a record of such an impairment" means has a history of, or has been misclassified as having, a mental or physical impairment that substantially limits one or more major life activities.

(iv) "Is regarded as having an impairment" means (A) has a physical or mental impairment that does not substantially limit major life activities but that is treated by a recipient as constituting such a limitation; (B) has a physical or mental impairment that substantially limits major life activities only as a result of the attitudes of others toward such impairment; or (C) has none of the impairments defined in paragraph (j)(2)(i) of this section but is treated by a recipient as having such an impairment.

(k) "Qualified handicapped person" means:

(1) With respect to employment, a handicapped person who, with reasonable accommodation, can perform the essential functions of the job in question;

(2) With respect to public preschool elementary, secondary, or adult educational services, a handicappped person (i) of an age during which nonhandicapped persons are provided such services, (ii) of any age during which it is mandatory under state law to provide such services to handicapped persons, or (iii) to whom a state is required to provide a free appropriate public education under section 612 of the Education of the Handicapped Act; and

(3) With respect to postsecondary and vocational education services, a handicapped person who meets the academic and technical standards requisite to admission or participation in the recipient's education program or activity;

(4) With respect to other services, a handicapped person who meets the essential eligibility requirements for the receipt of such services.

(l) "Handicap" means any condition or characteristic that renders a person a handicapped person as defined in paragraph (j) of this section.

§ 84.4 Discrimination prohibited.

(a) *General.* No qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity which receives or benefits from Federal financial assistance.

(b) *Discriminatory actions prohibited.* (1) A recipient, in providing any aid, benefit, or service, may not, directly or through contractual, licensing, or other arrangements, on the basis of handicap:

(i) Deny a qualified handicapped person the opportunity to participate in or benefit from the aid, benefit, or service;

(ii) Afford a qualified handicapped person an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded others;

(iii) Provide a qualified handicapped person with an aid, benefit, or service that is not as effective as that provided to others;

(iv) Provide different or separate aid, benefits, or services to handicapped persons or to any class of handicapped persons unless such action is necessary to provide qualified handicapped persons with aid, benefits, or services that are as effective as those provided to others;

(v) Aid or perpetuate discrimination against a qualified handicapped person by providing significant assistance to an agency, organization, or person that discriminates on the basis of handicap in providing any aid, benefit, or service to beneficiaries of the recipients program;

(vi) Deny a qualified handicapped person the opportunity to participate as a member of planning or advisory boards; or

(vii) Otherwise limit a qualified handicapped person in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving an aid, benefit, or service.

(2) For purposes of this part, aids, benefits, and services, to be equally effective, are not required to produce the identical result or level of achievement for handicapped and nonhandicapped persons, but must afford handicapped persons equal opportunity to obtain the same result, to gain the same benefit, or to reach the same level of achievement, in the most integrated setting appropriate to the person's needs.

(3) Despite the existence of separate or different programs or activities provided in accordance with this part, a recipient may not deny a qualified handicapped person the opportunity to participate in such programs or activities that are not separate or different.

(4) A recipient may not, directly or through contractual or other arrangements, utilize criteria or methods of administration (i) that have the effect of subjecting qualified handicapped persons to discrimination on the basis of handicap, (ii) that have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the recipient's program with respect to handicapped persons, or (iii) that perpetuate the discrimination of another recipient if both recipients are subject to common administrative control or are agencies of the same State.

(5) In determining the site or location of a facility, an applicant for assistance or a recipient may not make selections (i) that have the effect of excluding handicapped persons from, denying them the benefits of, or otherwise subjecting them to discrimination under any program or activity that receives or benefits from Federal financial assistance or (ii) that have the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the program or activity with respect to handicapped persons.

(6) As used in this section, the aid, benefit, or service provided under a program or activity receiving or benefiting from Federal financial assistance includes any aid, benefit, or service provided in or through a facility that has been constructed, expanded, altered, leased or rented, or otherwise acquired, in whole or in part, with Federal financial assistance.

(c) *Programs limited by Federal law.* The exclusion of nonhandicapped persons from the benefits of a program limited by Federal statute or executive order to handicapped persons or the exclusion of a specific class of handicapped persons from a program limited by Federal statute or executive order to a different class of handicapped persons is not prohibited by this part.

§ 84.5 Assurances required.

(a) *Assurances.* An applicant for Federal financial assistance for a program or activity to which this part applies shall submit an assurance, on a form specified by the Director, that the program will be operated in compliance with this part. An applicant may incorporate these assurances by reference in subsequent applications to the Department.

(b) *Duration of obligation.* (1) In the case of Federal financial assistance extended in the form of real property or to provide real property or structures on the property, the assurance will obligate the recipient or, in the case of a subsequent transfer, the transferee, for the period during which the real property or structures are used for the purpose for which Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits.

(2) In the case of Federal financial assistance extended to provide personal property, the assurance will obligate the recipient for the period during

which it retains ownership or possession of the property.

(3) In all other cases the assurance will obligate the recipient for the period during which Federal financial assistance is extended.

(c) *Covenants.* (1) Where Federal financial assistance is provided in the form of real property or interest in the property from the Department, the instrument effecting or recording this transfer shall contain a covenant running with the land to assure nondiscrimination for the period during which the real property is used for a purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits.

(2) Where no transfer of property is involved but property is purchased or improved with Federal financial assistance, the recipient shall agree to include the covenant described in paragraph (b)(2) of this section in the instrument effecting or recording any subsequent transfer of the property.

(3) Where Federal financial assistance is provided in the form of real property or interest in the property from the Department, the covenant shall also include a condition coupled with a right to be reserved by the Department to revert title to the property in the event of a breach of the covenant. If a transferee of real property proposes to mortgage or otherwise encumber the real property as security for financing construction of new, or improvement of existing, facilities on the property for the purposes for which the property was transferred, the Director may, upon request of the transferee and if necessary to accomplish such financing and upon such conditions as he or she deems appropriate, agree to forbear the exercise of such right to revert title for so long as the lien of such mortgage or other encumbrance remains effective.

§ 84.6 Remedial action, voluntary action, and self-evaluation.

(a) *Remedial action.* (1) If the Director finds that a recipient has discriminated against persons on the basis of handicap in violation of section 504 or this part, the recipient shall take such remedial action as the Director deems necessary to overcome the effects of the discrimination.

(2) Where a recipient is found to have discriminated against persons on the basis of handicap in violation of section 504 or this part and where another recipient exercises control over the recipient that has discriminated, the Director, where appropriate, may require either or both recipients to take remedial action.

(3) The Director may, where necessary to overcome the effects of discrimination in violation of section 504 or this part, require a recipient to take remedial action (i) with respect to handicapped persons who are no longer participants in the recipient's program but who were participants in the program when such discrimination occurred or (ii) with respect to handicapped persons who would have been participants in the program had the discrimination not occurred.

(b) *Voluntary action.* A recipient may take steps, in addition to any action that is required by this part, to overcome the effects of conditions that resulted in limited participation in the recipient's program or activity by qualified handicapped persons.

(c) *Self-evaluation.* (1) A recipient shall, within one year of the effective date of this part:

(i) Evaluate, with the assistance of interested persons, including handicapped persons or organizations representing handicapped persons, its current policies and practices and the effects thereof that do not or may not meet the requirements of this part;

(ii) Modify, after consultation with interested persons, including handicapped persons or organizations representing handicapped persons, any policies and practices that do not meet the requirements of this part; and

(iii) Take, after consultation with interested persons, including handicapped persons or organizations representing handicapped persons, appropriate remedial steps to eliminate the effects of any discrimination that resulted from adherence to these policies and practices.

(2) A recipient that employs fifteen or more persons shall, for at least three years following completion of the evaluation required under para-

graph (c)(1) of this section, maintain on file, make available for public inspection, and provide to the Director upon request: (i) A list of the interested persons consulted (ii) a description of areas examined and any problems identified, and (iii) a description of any modifications made and of any remedial steps taken.

§ 84.7 Designation of responsible employee and adoption of grievance procedures.

(a) *Designation of responsible employee.* A recipient that employs fifteen or more persons shall designate at least one person to coordinate its efforts to comply with this part.

(b) *Adoption of grievance procedures.* A recipient that employs fifteen or more persons shall adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of complaints alleging any action prohibited by this part. Such procedures need not be established with respect to complaints from applicants for employment or from applicants for admission to postsecondary educational institutions.

§ 84.8 Notice.

(a) A recipient that employs fifteen or more persons shall take appropriate initial and continuing steps to notify participants, beneficiaries, applications, and employees, including those with impaired vision or hearing, and unions or professional organizations holding collective bargaining or professional agreements with the recipient that it does not discriminate on the basis of handicap in violation of section 504 and this part. The notification shall state, where appropriate, that the recipient does not discriminate in admission or access to, or treatment or employment in, its programs and activities. The notification shall also include an identification of the responsible employee designated pursuant to § 84.7(a). A recipient shall make the initial notification required by this paragraph within 90 days of the effective date of this part. Methods of initial and continuing notification may include the posting of notices, publication in newspapers and magazines, placement of notices in recipients' publication, and distribution of memoranda or other written communications.

(b) If a recipient publishes or uses recruitment materials or publications containing general information that it makes available to participants, beneficiaries, applicants, or employees, it shall include in those materials or publications a statement of the policy described in paragraph (a) of this section. A recipient may meet the requirement of this paragraph either by including appropriate inserts in existing materials and publications or by revising and reprinting the materials and publications.

§ 84.9 Administrative requirements for small recipients.

The Director may require any recipient with fewer than fifteen employees, or any class of such recipients, to comply with §§ 84.7 and 84.8, in whole or in part, when the Director finds a violation of this part or finds that such compliance will not significantly impair the ability of the recipient or class of recipients to provide benefits or services.

§ 84.10 Effect of state or local law or other requirements and effect of employment opportunities.

(a) The obligation to comply with this part is not obviated or alleviated by the existence of any state or local law or other requirement that, on the basis of handicap, imposes prohibitions or limits upon the eligibility of qualified handicapped persons to receive services or to practice any occupation or profession.

(b) The obligation to comply with this part is not obviated or alleviated because employment opportunities in any occupation or profession are or may be more limited for handicapped persons than for nonhandicapped persons.

Subpart B—Employment Practices

§ 84.11 Discrimination prohibited.

(a) *General.* (1) No qualified handicapped person shall, on the basis of handicap, be subjected to discrimination in employment under any program or activity to which this part applies.

(2) A recipient that receives assistance under the Education of the Handicapped Act shall take positive steps to employ and advance in employment qualified handicapped persons in programs assisted under that Act.

(3) A recipient shall make all decisions concerning employment under any program or activity to which this part applies in a manner which ensures that discrimination on the basis of handicap does not occur and may not limit, segregate, or classify applicants or employees in any way that adversely affects their opportunities or status because of handicap.

(4) A recipient may not participate in a contractual or other relationship that has the effect of subjecting qualified handicapped applicants or employees to discrimination prohibited by this subpart. The relationships referred to in this paragraph include relationships with employment and referral agencies, with labor unions, with organizations providing or administering fringe benefits to employees of the recipient, and with organizations providing training and apprenticeship programs.

(b) *Specific activities.* The provisions of this subpart apply to:

(1) Recruitment, advertising, and the processing of applications for employment;

(2) Hiring, upgrading, promotion, award of tenure, demotion, transfer, layoff, termination, right of return from layoff and rehiring;

(3) Rates of pay or any other form of compensation and changes in compensation;

(4) Job assignments, job classifications, organizational structures, position descriptions, lines of progression, and seniority lists;

(5) Leaves of absense, sick leave, or any other leave;

(6) Fringe benefits available by virtue of employment, whether or not administered by the recipient;

(7) Selection and financial support for training, including apprenticeship, professional meetings, conferences, and other related activities, and selection for leaves of absence to pursue training;

(8) Employer sponsored activities, including social or recreational programs; and

(9) Any other term, condition, or privilege of employment.

(c) A recipient's obligation to comply with this subpart is not affected by any inconsistent term of any collective bargaining agreement to which it is a party.

§ 84.12 Reasonable accommodation.

(a) A recipient shall make reasonable accommodation to the known physical or mental limitations of an otherwise qualified handicapped applicant or employee unless the recipient can demonstrate that the accommodation would impose an undue hardship on the operation of its program.

(b) Reasonable accommodation may include: (1) Making facilities used by employees readily accessible to and usable by handicapped persons, and (2) job restructuring, part-time or modified work schedules, acquisition or modification of equipment or devices, the provision of readers or interpreters, and other similar actions.

(c) In determining pursuant to paragraph (a) of this section whether an accommodation would impose an undue hardship on the operation of a recipient's program, factors to be considered include:

(1) The overall size of the recipient's program with respect to number of employees, number and type of facilities, and size of budget;

(2) The type of the recipient's operation, including the composition and structure of the recipient's workforce; and

(3) The nature and cost of the accommodation needed.

(d) A recipient may not deny any employment opportunity to a qualified handicapped employee or applicant if the basis for the denial is the need to make reasonable accommodation to the physical or mental limitations of the employee or applicant.

§ 84.13 Employment criteria.

(a) A recipient may not make use of any employment test or other selection criterion that screens out or tends to screen out handicapped persons or any class of handicapped persons unless: (1) The test score or other selection criterion, as used by the recipient, is shown to be job-related for the position in question, and (2) alternative job-related tests or criteria that do not screen out or tend to screen out as many handicapped persons are not shown by the Director to be available.

(b) A recipient shall select and administer tests concerning employment so as best to ensure that, when administered to an applicant or employee who has a handicap that impairs sensory, manual, or speaking skills, the test results accurately reflect the applicant's or employee's job skills, aptitude, or whatever other factor the test purports to measure, rather than reflecting the applicant's or employee's impaired sensory, manual, or speaking skills (except where those skills are the factors that the test purports to measure).

§ 84.14 Preemployment inquiries.

(a) Except as provided in paragraphs (b) and (c) of this section, a recipient may not conduct a preemployment medical examination or may not make preemployment inquiry of an applicant as to whether the applicant is a handicapped person or as to the nature or severity of a handicap. A recipient may, however, make preemployment inquiry into an applicant's ability to perform job-related functions.

(b) When a recipient is taking remedial action to correct the effects of past discrimination pursuant to § 84.6 (a), when a recipient is taking voluntary action to overcome the effects of conditions that resulted in limited participation in its federally assisted program or activity pursuant to § 84.6(b), or when a recipient is taking affirmative action pursuant to section 503 of the Act, the recipient may invite applicants for employment to indicate whether and to what extent they are handicapped, *Provided,* That:

(1) The recipient states clearly on any written questionnaire used for this purpose or makes clear orally if no written questionnaire is used that the information requested is intended for use solely in connection with its remedial action obligations or its voluntary or affirmative action efforts; and

(2) The recipient states clearly that the information is being requested on a voluntary basis, that it will be kept confidential as provided in paragraph (d) of this section, that refusal to provide it will not subject the applicant or employee to any adverse treatment, and that it will be used only in accordance with this part.

(c) Nothing in this section shall prohibit a recipient from conditioning an offer of employment on the results of a medical examination conducted prior to the employee's entrance on duty, *Provided,* That: (1) All entering employees are subjected to such an examination regardless of handicap, and (2) the results of such an examination are used only in accordance with the requirements of this part.

(d) Information obtained in accordance with this section as to the medical condition or history of the applicant shall be collected and maintained on separate forms that shall be accorded confidentiality as medical records, except that:

(1) Supervisors and managers may be informed regarding restrictions on the work or duties of handicapped persons and regarding necessary accommodations;

(2) First aid and safety personnel may be informed, where appropriate, if the condition might require emergency treatment; and

(3) Government officials investigating compliance with the Act shall be provided relevant information upon request.

§§ 84.15—84.20 [Reserved]

Subpart C—Program Accessibility

§ 84.21 Discrimination prohibited.

No qualified handicapped person shall, because a recipient's facilities are inaccessible to or unusable by handicapped persons, be denied the benefits of, be excluded from participation in, or otherwise be subjected to discrimination under any program or activity to which this part applies.

§ 84.22 Existing facilities.

(a) *Program accessibility.* A recipient shall operate each program or activity to which this part applies so that the program or activity, when viewed in its entirety, is readily accessible to handicapped persons. This paragraph does not require a recipient to make each of its existing facilities or every part of a facility accessible to and usable by handicapped persons.

(b) *Methods.* A recipient may comply with the requirements of paragraph (a) of this section through such means as redesign of equipment, reassignment of classes or other services to accessible buildings, assignment of aides to beneficiaries, home visits, delivery of health, welfare, or other social services at alternate accessible sites, alteration of existing facilities and construction of new facilities in conformance with the requirements of § 84.23, or any other methods that result in making its program or activity accessible to handicapped persons. A recipient is not required to make structural changes in existing facilities where other methods are effective in achieving compliance with paragraph (a) of this section. In choosing among available methods for meeting the requirement of paragraph (a) of this section, a recipient shall give priority to those methods that offer programs and activities to handicapped persons in the most integrated setting appropriate.

(c) *Small health, welfare, or other social service providers.* If a recipient with fewer than fifteen employees that provides health, welfare, or other social services finds, after consultation with a handicapped person seeking its services, that there is no method of complying with paragraph (a) of this section other than making a significant alteration in its existing facilities, the recipient may, as an alternative, refer the handicapped person to other providers of those services that are accessible.

(d) *Time period.* A recipient shall comply with the requirement of paragraph (a) of this section within sixty days of the effective date of this part except that where structural changes in facilities are necessary, such changes shall be made within three years of the effective date of this part, but in any event as expeditiously as possible.

(e) *Transition plan.* In the event that structural changes to facilities are necessary to meet the requirement of paragraph (a) of this section, a recipient shall develop, within six months of the effective date of this part, a transition plan setting forth the steps necessary to complete such changes. The plan shall be developed with the assistance of interested persons, including handicapped persons or organizations representing handicapped persons. A copy of the transition plan shall be made available for public inspection. The plan shall, at a minimum:

(1) Identify physical obstacles in the recipient's facilities that limit the accessibility of its program or activity to handicappped persons;

(2) Describe in detail the methods that will be used to make the facilities accessible;

(3) Specify the schedule for taking the steps necessary to achieve full program accessibility and, if the time period of the transition plan is longer than one year, identify the steps of that will be taken during each year of the transition period; and

(4) Indicate the person responsible for implementation of the plan.

(f) *Notice.* The recipient shall adopt and implement procedures to ensure that interested persons, including persons with impaired vision or hearing, can obtain information as to the existence and location of services, activities, and facilities that are accessible to and usuable by handicapped persons.

§ 84.23 New construction.

(a) *Design and construction.* Each facility or part of a facility constructed by, on behalf of, or for the use of a recipient shall be designed and constructed in such manner that the facility or part of the facility is readily accessible to and usable by handicapped persons, if the construction was commenced after the effective date of this part.

(b) *Alteration.* Each facility or part of a facility which is altered by, on behalf of, or for the use of a recipient after the effective date of this part in a manner that affects or could affect the usability of the facility or part of the facility shall, to the maximum extent feasible, be altered in such manner that the altered portion of the facility is readily accessible to and usable by handicapped persons.

(c) *American National Standards Institute accessibility standards.* Design, construction, or alteration of facilities in conformance with the "American National Standard Specifications for Making Buildings and Facilities Accessible to, and Usable by, the Physically Handicapped," published by the American National Standards Institute, Inc. (ANSI A117.1-1961 (R1971)).[1] which is incorporated by reference in this part, shall constitute compliance with paragraphs (a) and (b) of this section. Departures from particular requirements of those standards by the use of other methods shall be permitted when it is clearly evident that equivalent access to the facility or part of the facility is thereby provided.

§§ 84.24—84.30 [Reserved]

Subpart D—Preschool, Elementary, and Secondary Education

§ 84.31 Application of this subpart.

Subpart D applies to preschool, elementary, secondary, and adult education programs and activities that receive or benefit from Federal financial assistance and to recipients that operate, or that receive or benefit from Federal financial assistance for the operation of, such programs or activities.

§ 84.32 Location and notification.

A recipient that operates a public elementary or secondary education program shall annually:

(a) Undertake to identify and locate every qualified handicapped person residing in the recipient's jurisdiction who is not receiving a public education; and

(b) Take appropriate steps to notify handicapped persons and their parents or guardians of the recipient's duty under this subpart.

§ 84.33 Free appropriate public education.

(a) *General.* A recipient that operates a public elementary or secondary education program shall provide a free appropriate public education to each qualified handicapped person who is in the recipient's jurisdiction, regardless of the nature or severity of the person's handicap.

(b) *Appropriate education.* (1) For the purpose of this subpart, the provision of an appropraite education is the provision of regular or special education and related aids and services that (i) are designed to meet individual educational needs of handicapped persons as adequately as the needs of nonhandicapped persons are met and (ii) are based upon adherence to procedures that satisfy the requirements of §§ 84.34, 84.35, and 84.36.

(2) Implementation of an individualized education program developed in accordance with the Education of the Handicapped Act is one means of meeting the standard established in paragraph (b)(1)(i) of this section.

(3) A recipient may place a handicapped person in or refer such person to a program other than the one that it operates as its means of carrying out the requirements of this subpart. If so, the recipient remains responsible for ensuring that the requirements of this subpart are met with respect to any handicapped person so placed or referred.

(c) *Free education*—(1) *General.* For the purpose of this section, the provision of a free education is the provision of educational and related services without cost to the handicapped person or to his or her parents or guardian, except for those fees that are imposed on non-handicapped persons or their parents or guardian. It may consist either of the provision of free services or, if a recipient places a handicapped person in or refers such person to a program not operated by the recipient as its means of carrying out the requirements of this subpart, of payment for the costs of the program. Funds available from any public or private agency may be used to meet the requirements of this subpart. Nothing in this section shall be construed to relieve an insurer or similar third party from an otherwise valid obligation to provide or pay for services provided to a handicapped person.

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[1] Copies obtainable from American National Standards Institute, Inc., 1430 Broadway, New York, N.Y. 10018.

(2) *Transportation.* If a recipient places a handicapped person in or refers such person to a program not operated by the recipient as its means of carrying out the requirements of this subpart, the recipient shall ensure that adequate transportation to and from the program is provided at no greater cost than would be incurred by the person or his or her parents or guardian if the person were placed in the program operated by the recipient.

(3) *Residential placement.* If placement in a public or private residential program is necessary to provide a free appropriate public education to a handicapped person because of his or her handicap, the program, including non-medical care and room and board, shall be provided at no cost to the person or his or her parents or guardian.

(4) *Placement of handicapped persons by parents.* If a recipient has made available, in conformance with the requirements of this section and § 84.34, a free appropriate public education to a handicapped person and the person's parents or guardian choose to place the person in a private school, the recipient is not required to pay for the person's education in the private school. Disagreements between a parent or guardian and a recipient regarding whether the recipient has made such a program available or otherwise regarding the question of financial responsibility are subject to the due process procedures of § 84.36.

(d) *Compliance.* A recipient may not exclude any qualified handicapped person from a public elementary or secondary education after the effective date of this part. A recipient that is not, on the effective date of this regulation, in full compliance with the other requirements of the preceding paragraphs of this section shall meet such requirements at the earliest practicable time and in no event later than September 1, 1978.

§ 84.34 Educational setting.

(a) *Academic setting.* A recipient to which this subpart applies shall educate, or shall provide for the education of, each qualified handicapped person in its jurisdiction with persons who are not handicapped to the maximum extent appropriate to the needs of the handicapped person. A recipient shall place a handicapped person in the regular educational environment operated by the recipient unless it is demonstrated by the recipient that the education of the person in the regular environment with the use of supplementary aids and services cannot be achieved satisfactorily. Whenever a recipient places a person in a setting other than the regular educational environment pursuant to this paragraph, it shall take into account the proximity of the alternate setting to the person's home.

(b) *Nonacademic settings.* In providing or arranging for the provision of nonacademic and extracurricular services and activities, including meals, recess periods, and the services and activities set forth in § 84.37(a)(2), a recipient shall ensure that handicapped persons participate with nonhandicapped persons in such activities and services to the maximum extent appropriate to the needs of the handicapped person in question.

(c) *Comparable facilities.* If a recipient, in compliance with paragraph (a) of this section, operates a facility that is identifiable as being for handicapped persons, the recipient shall ensure that the facility and the services and activities provided therein are comparable to the other facilities, services, and activities of the recipient.

§ 84.35 Evaluation and placement.

(a) *Preplacement evaluation.* A recipient that operates a public elementary or secondary education program shall conduct an evaluation in accordance with the requirements of paragraph (b) of this section of any person who, because of handicap, needs or is believed to need special education or related services before taking any action with respect to the initial placement of the person in a regular or special education program and any subsequent significant change in placement.

(b) *Evaluation procedures.* A recipient to which this subpart applies shall establish standards and procedures for the evaluation and placement of persons who, because of handicap, need or are believed to need special education or related services which ensure that:

(1) Tests and other evaluation materials have been validated for the specific purpose for which they are used and are administered by trained personnel in conformance with the instructions provided by their producer;

(2) Tests and other evaluation materials include those tailored to assess specific areas of educational need and not merely those which are designed to provide a single general intelligence quotient; and

(3) Tests are selected and administered so as best to ensure that, when a test is administered to a student with impaired sensory, manual, or speaking skills, the test results accurately reflect the student's aptitude or achievement level or whatever other factor the test purports to measure, rather than reflecting the student's impaired sensory, manual, or speaking skills (except where those skills are the factors that the test purports to measure).

(c) *Placement procedures.* In interpreting evaluation data and in making placement decisions, a recipient shall (1) draw upon information from a variety of sources, including aptitude and achievement tests, teacher recommendations, physical condition, social or cultural background, and adaptive behavior, (2) establish procedures to ensure that information obtained from all such sources is documented and carefully considered, (3) ensure that the placement decision is made by a group of persons, including persons knowledgeable about the child, the meaning of the evaluation data, and the placement options, and (4) ensure that the placement decision is made in conformity with § 84.34.

(d) *Reevaluation.* A recipient to which this section applies shall establish procedures, in accordance with paragraph (b) of this section, for periodic reevaluation of students who have been provided special education and related services. A reevaluation procedure consistent with the Education for the Handicapped Act is one means of meeting this requirement.

§ 84.36 Procedural safeguards.

A recipient that operates a public elementary or secondary education program shall establish and implement, with respect to actions regarding the identification, evaluation, or educational placement of persons who, because of handicap, need or are believed to need special instruction or related services, a system of procedural safeguards that includes notice, an opportunity for the parents or guardian of the person to examine relevant records, an impartial hearing with opportunity for participation by the person's parents or guardian and representation by counsel, and a review procedure. Compliance with the procedural safeguards of section 615 of the Education of the Handicapped Act is one means of meeting this requirement.

§ 84.37 Nonacademic services.

(a) *General.* (1) A recipient to which this subpart applies shall provide nonacademic and extracurricular services and activities in such manner as is necessary to afford handicapped students an equal opportunity for participation in such services and activities.

(2) Nonacademic and extracurricular services and activities may include counseling services, physical recreational athletics, transportation, health services, recreational activities, special interest groups or clubs sponsored by the recipients, referrals to agencies which provide assistance to handicapped persons, and employment of students, including both employment by the recipient and assistance in making available outside employment.

(b) *Counseling services.* A recipient to which this subpart applies that provides personal, academic, or vocational counseling, guidance, or placement services to its students shall provide these services without discrimination on the basis of handicap. The recipient shall ensure that qualified handicapped students are not counseled toward more restrictive career objectives than are nonhandicapped students with similar interests and abilities.

(c) *Physical education and athletics.* (1) In providing physical education courses and athletics and similar programs and activities to any of its students, a recipient to which this subpart applies may not discriminate on the basis of handicap. A recipient that offers physical education courses or that operates or sponsors interscholastic, club, or intramural athletics shall provide to qualified handicapped students an equal opportunity for participation in these activities.

(2) A recipient may offer to handicapped students physical education and athletic activities that are separate or different from those offered to nonhandicapped students only if separation or differentiation is consistent with the requirements of § 84.34 and only if no qualified handicapped student is denied the opportunity to compete for teams or to participate in courses that are not separate or different.

§ 84.38 Preschool and adult education programs.

A recipient to which this subpart applies that operates a preschool education or day care program or activity or an adult education program or activity may not, on the basis of handicap, exclude qualified handicapped persons from the program or activity and shall take into account the needs of such persons in determining the aid, benefits, or services to be provided under the program or activity.

§ 84.39 Private education programs.

(a) A recipient that operates a private elementary or secondary education program may not, on the basis of handicap, exclude a qualified handicapped person from such program if the person can, with minor adjustments, be provided an appropriate education, as defined in § 84.33(b)(1), within the recipient's program.

(b) A recipient to which this section applies may not charge more for the provision of an appropriate education to handicapped persons than to nonhandicapped persons except to the extent that any additional charge is justified by a substantial increase in cost to the recipient.

(c) A recipient to which this section applies that operates special education programs shall operate such programs in accordance with the provisions of §§ 84.35 and 84.36. Each recipient to which this section applies is subject to the provisions of §§ 84.34, 84.37, and 84.38.

§ 84.40 [Reserved]

Subpart E—Postsecondary Education

§ 84.41 Application of this subpart.

Subpart E applies to postsecondary education programs and activities, including postsecondary vocational education programs and activities, that receive or benefit from Federal financial assistance and to recipients that operate, or that receive or benefit from Federal financial assistance for the operation of, such programs or activities.

§ 84.42 Admissions and recruitment.

(a) *General.* Qualified handicapped persons may not, on the basis of handicap, be denied admission or be subjected to discrimination in admission or recruitment by a recipient to which this subpart applies.

(b) *Admissions.* In administering its admission policies, a recipient to which this subpart applies:

(1) May not apply limitations upon the number or proportion of handicapped persons who may be admitted;

(2) May not make use of any test or criterion for admission that has a disproportionate, adverse effect on handicapped persons or any class of handicapped persons unless (i) the test or criterion, as used by the recipient, has been validated as a predictor of success in the education program or activity in question and (ii) alternate tests or criteria that have a less disproportionate, adverse effect are not shown by the Director to be available.

(3) Shall assure itself that (i) admissions tests are selected and administered so as best to ensure that, when a test is administered to an applicant who has a handicap that impairs sen-

sory, manual, or speaking skills, the test results accurately reflect the applicant's aptitude or achievement level or whatever other factor the test purports to measure, rather than reflecting the applicant's impaired sensory, manual, or speaking skills (except where those skills are the factors that the test purports to measure); (ii) admissions tests that are designed for persons with impaired sensory, manual, or speaking skills are offered as often and in as timely a manner as are other admissions tests; and (iii) admissions tests are administered in facilities that, on the whole, are accessible to handicapped persons; and

(4) Except as provided in paragraph (c) of this section, may not make preadmission inquiry as to whether an applicant for admission is a handicapped person but, after admission, may make inquiries on a confidential basis as to handicaps that may require accommodation.

(c) *Preadmission inquiry exception.* When a recipient is taking remedial action to correct the effects of past discrimination pursuant to § 84.6(a) or when a recipient is taking voluntary action to overcome the effects of conditons that resulted in limited participation in its federally assisted program or activity pursuant to § 84.6(b), the recipient may invite applicants for admission to indicate whether and to what extent they are handicapped, *Provided,* That:

(1) The recipient states clearly on any written questionnaire used for this purpose or makes clear orally if no written questionnaire is used that the information requested is intended for use solely in connection with its remedial action obligations or its voluntary action efforts; and

(2) The recipient states clearly that the information is being requested on a voluntary basis, that it will be kept confidential, that refusal to provide it will not subject the applicant to any adverse treatment, and that it will be used only in accordance with this part.

(d) *Validity studies.* For the purpose of paragraph (b)(2) of this section, a recipient may base prediction equations on first year grades, but shall conduct periodic validity studies against the criterion of overall success in the education program or activity in question in order to monitor the general validity of the test scores.

§ 84.43 Treatment of students; general.

(a) No qualified handicapped student shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any academic, research, occupational training, housing, health insurance, counseling, financial aid, physical education, athletics, recreation, transportation, other extracurricular, or other posesecodary education program or activity to which this subpart applies.

(b) A recipient to which this subpart applies that considers participation by students in education programs or activities not operated wholly by the recipient as part of, or equivalent to, and education program or activity operated by the recipient shall assure itself that the other education program or activity, as a whole, privides an equal opportunity for the participation of qualified handicapped persons.

(c) A recipient to which this subpart applies may not, on the basis of handicap, exclude any qualified handicapped student from any course, course of study, or other part of its education program or activity.

(d) A recipient to which this subpart applies shall operate its programs and activities in the most integrated setting appropriate.

§ 84.44 Academic adjustments.

(a) *Academic requirements.* A recipient to which this subpart applies shall make such modifications to its academic requirements as are necessary to ensure that such requirements do not discriminate or have the effect of discriminating, on the basis of handicap, against a qualified handicapped applicant or student. Academic requirements that the recipient can demonstrate are essential to the program of instruction being pursued by such student or to any directly related licensing requirement will not be regarded as discriminatory within the meaning of this section. Modifications may include changes in the length of time permitted for the completion of degree requirements, substitution of specific courses required for the completion of degree requirements, and adaptation of the manner in which specific courses are conducted.

(b) *Other rules.* A recipient to which this subpart applies may not impose upon handicapped students other rules, such as the prohibition of tape recorders in classrooms or of dog guides in campus buildings, that have the effect of limiting the participation of handicapped students in the recipient's education program or activity.

(c) *Course examinations.* In its course examinations or other procedures for evaluating students' academic achievement in its program, a recipient to which this subpart applies shall provide such methods for evaluating the achievement of students who have a handicap that impairs sensory, manual, or speaking skills as will best ensure that the results of the evaluation represents the student's achievement in the course, rather than reflecting the student's impaired sensory, manual, or speaking skills (except where such skills are the factors that the test purports to measure).

(d) *Auxiliary aids.* (1) A recipient to which this subpart applies shall take such steps as are necessary to ensure that no handicapped student is denied the benefits of, excluded from participation in, or otherwise subjected to discrimination under the education program or activity operated by the recipient because of the absence of educational auxiliary aids for students with impaired sensory, manual, or speaking skills.

(2) Auxiliary aids may include taped texts, interpreters or other effective methods of making orally delivered materials available to students with hearing impairments, readers in libraries for students with visual impairments, classroom equipment adapted for use by students with manual impairments, and other similar services and actions. Recipients need not provide attendants, individually prescribed devices, readers for personal use or study, or other devices or services of a personal nature.

§ 84.45 Housing.

(a) *Housing provided by the recipient.* A recipient that provides housing to its nonhandicapped students shall provide comparable, convenient, and accessible housing to handicapped students at the same cost as to others. At the end of the transition period provided for in Subpart C, such housing shall be available in sufficient quantity and variety so that the scope of handicapped students' choice of living accommodations is, as a whole, comparable to that of nonhandicapped students.

(b) *Other housing.* A recipient that assists any agency, organization, or person in making housing available to any of its students shall take such action as may be necessary to assure itself that such housing is, as a whole, made available in a manner that does not result in discrimination on the basis of handicap.

§ 84.46 Financial and employment assistance to students.

(a) *Provision of financial assistance.* (1) In providing financial assistance to qualified handicapped persons, a recipient to which this subpart applies may not (i), on the basis of handicap, provide less assistance than is provided to nonhandicapped persons, limit eligibility for assistance, or otherwise discriminate or (ii) assist any entity or person that provides assistance to any of the recipient's students in a manner that discriminates against qualified handicapped persons on the basis of handicap.

(2) A recipient may administer or assist in the administration of scholarships, fellowships, or other forms of financial assistance established under wills, trusts, bequests, or similar legal instruments that require awards to be made on the basis of factors that discriminate or have the effect of discriminating on the basis of handicap only if the overall effect of the award of scholarships, fellowships, and other forms of financial assistance is not discriminatory on the basis of handicap.

(b) *Assistance in making available outside employment.* A recipient that assists any agency, organization, or person in providing employment opportunities to any of its students shall assure itself that such employment opportunities, as a whole, are made available in a manner that would not violate Subpart B if they were provided by the recipient.

(c) *Employment of students by recipients.* A recipient that employs any of its students may not do so in a manner that violates Subpart B.

§ 84.47 Nonacademic services.

(a) *Physical education and athletics.* (1) In providing physical education courses and athletics and similar programs and activities to any of its students, a recipient to which this subpart applies may not disacriminate on the basis of handicap. A recipient that offers physical education courses or that operates or sponsors intercollegiate, club, or intramural athletics shall provide to qualified handicapped students an equal opportunity for participation in these activities.

(2) A recipient may offer to handicapped students physical education and athletic activities that are separate or different only if separation or differentiation is consistent with the requirements of § 84.43(d) and only if no qualified handicapped student is denied the opportunity to compete for teams or to participate in courses that are not separate or different.

(b) *Counseling and placement services.* A recipient to which this subpart applies that provides personal, academic, or vocational counseling, guidance, or placement services to its students shall provide these services without discrimination on the basis of handicap. The recipient shall ensure that qualified handicapped students are not counseled toward more restrictive career objectives than are nonhandicapped students with similar interests and abilities. This requirement does not preclude a recipient from providing factual information about licensing and certification requirements that may present obstacles to handicapped persons in their pursuit of particular careers.

(c) *Social organizations.* A recipient that provides significant assistance to fraternities, sororities, or similar organizations shall assure itself that the membership practices of such organizations do not permit discrimination otherwise prohibited by this subpart.

§§ 84.48—84.50 [Reserved]

Subpart F—Health, Welfare, and Social Services

§ 84.51 Application of this subpart.

Subpart F applies to health, welfare, and other social service programs and activities that receive or benefit from Federal financial assistance and to recipients that operate, or that receive or benefit from Federal financial assistance for the operation of, such programs or activities.

§ 84.52 Health, welfare, and other social services.

(a) *General.* In providing health, welfare, or other social services or benefits, a recipient may not, on the basis of handicap:

(1) Deny a qualified handicapped person these benefits or services;

(2) Afford a qualified handicapped person an opportunity to receive benefits or services that is not equal to that offered nonhandicapped persons;

(3) Provide a qualified handicapped person with benefits or services that are not as effective (as defined in § 84.4(b)) as the benefits or services provided to others;

(4) Provide benefits or services in a manner that limits or has the effect of limiting the participation of qualified handicapped persons; or

(5) Provide different or separate benefits or services to handicapped persons except where necessary to provide qualified handicapped persons with benefits and services that are as effective as those provided to others.

(b) *Notice.* A recipient that provides notice concerning benefits or services or written material concerning waivers of rights or consent to treatment shall take such steps as are necessary to ensure that qualified handicapped persons, including those with impaired sensory or speaking skills, are not denied effective notice because of their handicap.

(c) *Emergency treatment for the hearing impaired.* A recipient hospital that provides health services or benefits shall establish a procedure for effective communication with persons with impaired hearing for the purpose of providing emergency health care.

(d) ***Auxiliary aids.*** (1) A recipient to which this subpart applies that employs fifteen or more persons shall provide appropriate auxiliary aids to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

(2) The Director may require recipients with fewer than fifteen employees to provide auxiliary aids where the provision of aids would not significantly impair the ability of the recipient to provide its benefits or services.

(3) For the purpose of this paragraph, auxiliary aids may include brailled and taped material, interpreters, and other aids for persons with impaired hearing or vision.

§ 84.53 Drug and alcohol addicts.

A recipient to which this subpart applies that operates a general hospital or outpatient facility may not discriminate in admission or treatment against a drug or alcohol abuser or alcoholic who is suffering from a medical condition, because of the person's drug or alcohol abuse or alcoholism.

§ 84.54 Education of institutionalized persons.

A recipient to which this subpart applies and that operates or supervises a program or activity for persons who are institutionalized because of handicap shall ensure that each qualified handicapped person, as defined in § 84.3(k)(2), in its program or activity is provided an appropriate education, as defined in § 84.33(b). Nothing in this section shall be interpreted as altering in any way the obligations of recipients under Subpart D.

§ 84.55 Procedures relating to health care for handicapped infants.

(a) *Infant Care Review Committees.* The Department encourages each recipient health care provider that provides health care services to infants in programs receiving Federal financial assistance to establish an Infant Care Review Committee (ICRC) to assist the provider in delivering health care and related services to infants and in complying with this part. The purpose of the committee is to assist the health care provider in the development of standards, policies and procedures for providing treatment to handicapped infants and in making decisions concerning medically beneficial treatment in specific cases. While the Department recognizes the value of ICRC's in assuring appropriate medical care to infants, such committees are not required by this section. An ICRC should be composed of individuals representing a broad range of perspectives, and should include a practicing physician, a representative of a disability organization, a practicing nurse, and other individuals. A suggested model ICRC is set forth in paragraph (f) of this section.

(b) *Posting of informational notice.* (1) Each recipient health care provider that provides health care services to infants in programs or activities receiving Federal financial assistance shall post and keep posted in appropriate places an informational notice.

(2) The notice must be posted at location(s) where nurses and other medical professionals who are engaged in providing health care and related services to infants will see it. To the extent it does not impair accomplishment of the requirement that copies of the notice be posted where such personnel will see it, the notice need not be posted in area(s) where parents of infant patients will see it.

(3) Each health care provider for which the content of the following notice (identified as Notice A) is truthful may use Notice A. For the content of the notice to be truthful: (i) The provider must have a policy consistent with that stated in the notice; (ii) the provider must have a procedure for review of treatment deliberations and decisions to which the notice applies, such as (but not limited to) an Infant Care Review Committee; and (iii) the statements concerning the identity of callers and retaliation are truthful.

Notice A:

PRINCIPLES OF TREATMENT OF DISABLED INFANTS

> It is the policy of this hospital, consistent with Federal law, that, nourishment and medically beneficial treatment (as determined with respect for reasonable medical judgments) should not be withheld from handicapped infants solely on the basis of their present or anticipated mental or physical impairments.
>
> This Federal law, section 504 of the Rehabilitation Act of 1973, prohibits discrimination on the basis of handicap in programs or activities receiving Federal financial assistance. For further information, or to report suspected noncompliance, call:
>
> [Identify designated hospital contact point and telephone number] or
>
> [Identify appropriate child protective services agency and telephone number] or
>
> U.S. Department of Health and Human Services (HHS): 800-368-1019 (Toll-free; available 24 hours a day; TDD capability).
>
> The identity of callers will be held confidential. Retaliation by this hospital against any person for providing information about possible noncompliance is prohibited by this hospital and Federal regulations.

(4) Health care providers other than those described in paragraph (b)(3) of this section must post the following notice (identified as Notice B):

Notice B:

PRINCIPLES OF TREATMENT OF DISABLED INFANTS

> Federal law prohibits discrimination on the basis of handicap. Under this law, nourishment and medically beneficial treatment (as determined with respect for reasonable medical judgments) should not be withheld from handicapped infants solely on the basis of their present or anticipated mental or physical impairments.
>
> This Federal law, section 504 of the Rehabilitation Act of 1973, applies to programs or activities receiving Federal financial assistance. For further information, or to report suspected noncompliance, call:
>
> [Identify appropriate child protective services agency and telephone number] or
>
> U.S. Department of Health and Human Services (HHS): 800-368-1019 (Toll-free; available 24 hours a day; TDD capability)
>
> The identity of callers will be held confidential. Federal regulations prohibit retaliation by this hospital against any person who provides information about possible violations.

(5) The notice may be no smaller than 5 by 7 inches, and the type size no smaller than that generally used for similar internal communications to staff. The recipient must insert the specified information on the notice it selects. Recipient hospitals in Washington, D.C. must list 863-0100 as the telephone number for HHS. No other alterations may be made to the notice. Copies of the notices may be obtained from the Department of Health and Human Services upon request, or the recipient may produce its own notices in conformance with the specified wording.

(c) *Responsibilities of recipient state child protective services agencies.* (1) Within 60 days of the effective date of this section, each recipient state child protective services agency shall establish and maintain in written form methods of administration and procedures to assure that the agency utilizes its full authority pursuant to state law to prevent instances of unlawful medical neglect of handicapped infants. These methods of administration and procedures shall include:

(i) A requirement that health care providers report on a timely basis to the state agency circumstances which they determine to constitute known or suspected instances of unlawful medical neglect of handicapped infants;

(ii) A method by which the state agency can receive reports of suspected unlawful medical neglect of handicapped infants from health care providers, other individuals, and the Department on a timely basis;

(iii) Immediate review of reports of suspected unlawful medical neglect of handicapped infants and, where appropriate, on-site investigation of such reports;

(iv) Provision of child protective services to such medically neglected handicapped infants, including, where appropriate, seeking a timely court order to compel the provision of necessary nourishment and medical treatment; and

(v) Timely notification to the responsible Department official of each report of suspected unlawful medical neglect involving the withholding, solely on the basis of present or anticipated physical or mental impairments, of treatment or nourishment from a handicapped infant who, in spite of such impairments, will medically benefit from the treatment or nourishment, the steps taken by the state agency to investigate such report, and the state agency's final disposition of such report.

(2) Whenever a hospital at which an infant who is the subject of a report of suspected unlawful medical neglect is being treated has an Infant Care Review Committee (ICRC) the Department encourages the state child protective services agency to consult with the ICRC in carrying out the state agency's authorities under its state law and methods of administration. In developing its methods of administration and procedures, the Department encourages child protective services agencies to adopt guidelines for investigations similar to those of the Department regarding the involvement of ICRC's.

(d) *Expedited access to records.* Access to pertinent records and facilities of a recipient pursuant to 45 CFR 80.6(c) (made applicable to this part by 45 CFR 84.61) shall not be limited to normal business hours when, in the judgment of the responsible Department official, immediate access is necessary to protect the life or health of a handicapped individual.

(e) *Expedited action to effect compliance.* The requirement of 45 CFR 80.8(d)(3) pertaining to notice to recipients prior to the initiation of action to effect compliance (made applicable to this part by 45 CFR 84.61) shall not apply when, in the judgment of the responsible Department official, immediate action to effect compliance is necessary to protect the life or health of a handicapped individual. In such cases the recipient will, as soon as practicable, be given oral or written notice of its failure to comply, of the action to be taken to effect compliance, and its continuing opportunity to comply voluntarily.

(f) *Model Infant Care Review Committee.* Recipient health care providers wishing to establish Infant Care Review Committees should consider adoption of the following model. This model is advisory. Recipient health care providers are not required to establish a review committee or, if one is established, to adhere to this model. In seeking to determine compliance with this part, as it relates to health care for handicapped infants, by health care providers that have an ICRC established and operated substantially in accordance with this model, the Department will, to the extent possible, consult with the ICRC.

(1) *Establishment and purpose.* (i) The hospital establishes an Infant Care Review Committee (ICRC) or joins with one or more other hospitals to create a joint ICRC. The establishing document will state that the ICRC is for the purpose of facilitating the development and implementation of standards, policies and procedures designed to assure that, while respecting reasonable medical judgments, treatment and nourishment not be withheld, solely on the basis of present or anticipated physical or mental impairments, from handicapped infants who, in spite of such impairments, will benefit medically from the treatment or nourishment.

(ii) The activities of the ICRC will be guided by the following principles:

(A) The interpretative guidelines of the Department relating to the applicability of this part to health care for handicapped infants.

(B) As stated in the "Principles of Treatment of Disabled Infants" of the coalition of major medical and disability organizations, including the American Academy of Pediatrics, National Association of Children's Hospitals and Related Institutions, Association for Retarded Citizens, Down's Syndrome Congress, Spina Bifida Association, and others:

> When medical care is clearly beneficial, it should always be provided. When appropriate medical care is not available, arrangements should be made to transfer the infant to an appropriate medical facility. Consideration such as anticipated or actual limited potential of an individual and present or future lack of available community resources are irrelevant and must not determine the decisions concerning medical care. The individual's medical condition should be the sole focus of the decision. These are very strict standards.
>
> It is ethically and legally justified to withhold medical or surgical procedures which are clearly futile and will only prolong the act of dying. However, supportive care should be provided, including sustenance as

medically indicated and relief of pain and suffering. The needs of the dying person should be respected. The family also should be supported in its grieving.

In cases where it is uncertain whether medical treatment will be beneficial, a person's disability must not be the basis for a decision to withhold treatment. At all times during the process when decisions are being made about the benefit or futility of medical treatment, the person should be cared for in the medically most appropriate ways. When doubt exists at any time about whether to treat, a presumption always should be in favor of treatment.

(C) As stated by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research:

> This [standard for providing medically beneficial treatment] is a very strict standard in that it excludes consideration of the negative effects of an impaired child's life on other persons, including parents, siblings, and society. Although abiding by this standard may be difficult in specific cases, it is all too easy to undervalue the lives of handicapped infants; the Commission finds it imperative to counteract this by treating them no less vigorously than their healthy peers or than older children with similar handicaps would be treated.

(iii) The ICRC will carry out its purposes by:

(A) Recommending institutional policies concerning the withholding or withdrawal of medical or surgical treatments to infants, including guidelines for ICRC action for specific categories of life-threatening conditions affecting infants;

(B) Providing advice in specific cases when decisions are being considered to withhold or withdraw from infant life-sustaining medical or surgical treatment; and

(C) Reviewing retrospectively on a regular basis infant medical records in situations in which life-sustaining medical or surgical treatment has been withheld or withdrawn.

(2) *Organization and staffing.* The ICRC will consist of at least 7 members and include the following:

(i) A practicing physician (e.g., a pediatrician, a neonatologist, or a pediatric surgeon),

(ii) A practicing nurse,

(iii) A hospital administrator,

(iv) A representative of the legal profession,

(v) A representative of a disability group, or a developmental disability expert,

(vi) A lay community member, and

(vii) A member of a facility's organized medical staff, who shall serve as chairperson.

In connection with review of specific cases, one member of the ICRC shall be designated to act as "special advocate" for the infant, as provided in paragraph (f)(3)(ii)(E) of the section. The hospital will provide staff support for the ICRC, including legal counsel. The ICRC will meet on a regular basis, or as required below in connection with review of specific cases. It shall adopt or recommend to the appropriate hospital official or body such administrative policies as terms of office and quorum requirements. The ICRC will recommend procedures to ensure that both hospital personnel and patient families are fully informed of the existence and functions of the ICRC and its availability on a 24-hour basis.

(3) *Operation of ICRC*—(i) *Prospective policy development.* (A) The ICRC will develop and recommend for adoption by the hospital institutional policies concerning the withholding or withdrawal of medical treatment for infants with life-threatening conditions. These will include guidelines for management of specific types of cases or diagnoses, for example, Down's syndrome and spina bifida, and procedures to be followed in such recurring circumstances as, for example, brain death and parental refusal to consent to life-saving treatment. The hospital, upon recommendation of the ICRC, may require attending physicians to notify the ICRC of the presence in the facility of an infant with a diagnosis specified by the ICRC, e.g., Down's syndrome and spina bifida.

(B) In recommending these policies and guidelines, the ICRC will consult with medical and other authorities on issues involving disabled individuals, e.g., neonatologists, pediatric surgeons, county and city agencies which provide services for the disabled, and disability advocacy organizations. It will also consult with appropriate committees of the medical staff, to ensure that the ICRC policies and guidelines build on existing staff by-laws, rules and regulations concerning consultations and staff membership requirements. The ICRC will also inform and educate hospital staff on the policies and guidelines it develops.

(ii) *Review of specific cases.* In addition to regularly scheduled meetings, interim ICRC meetings will take place under specified circumstances to permit review of individual cases. The hospital will, to the extent possible, require in each case that life-sustaining treatment be continued, until the ICRC can review the case and provide advice.

(A) Interim ICRC meetings will be convened within 24 hours (or less if indicated) when there is disagreement between the family of an infant and the infant's physician as to the withholding or withdrawal of treatment, when a preliminary decision to withhold or withdraw life-sustaining treatment has been made in certain categories of cases identified by the ICRC, when there is disagreement between members of the hospital's medical and/or nursing staffs, or when otherwise appropriate.

(B) Such interim ICRC meetings will take place upon the request of any member of the ICRC or hospital staff or parent or guardian of the infant. The ICRC will have procedures to preserve the confidentiality of the identity of persons making such requests, and such persons shall be protected from reprisal. When appropriate, the ICRC or a designated member will inform the requesting individual of the ICRC's recommendation.

(C) The ICRC may provide for telephone and other forms of review when the timing and nature of the case, as identified in policies developed by the ICRC, make the convening of an interim meeting impracticable.

(D) Interim meetings will be open to the affected parties. The ICRC will ensure that the interests of the parents, the physician, and the child are fully considered; that family members have been fully informed of the patient's condition and prognosis; that they have been provided with a listing which describes the services furnished by parent support groups and public and private agencies in the geographic vicinity to infants with conditions such as that before the ICRC; and that the ICRC will facilitate their access to such services and groups.

(E) To ensure a comprehensive evaluation of all options and factors pertinent to the committee's deliberations, the chairperson will designate one member of the ICRC to act, in connection with that specific case, as special advocate for the infant. The special advocate will seek to ensure that all considerations in favor of the provision of life-sustaining treatment are fully evaluated and considered by the ICRC.

(F) In cases in which there is disagreement on treatment between a physician and an infant's family, and the family wishes to continue life-sustaining treatment, the family's wishes will be carried out, for as long as the family wishes, unless such treatment is medically contraindicated. When there is physician/family disagreement and the family refuses consent to life-sustaining treatment, and the ICRC, after due deliberation, agrees with the family, the ICRC will recommend that the treatment be withheld. When there is physician/family disagreement and the family refuses consent, but the ICRC disagrees with the family, the ICRC will recommend to the hospital board or appropriate official that the case be referred immediately to an appropriate court or child protective agency, and every effort shall be made to continue treatment, preserve the status quo, and prevent worsening of the infant's condition until such time as the court or agency renders a decision or takes other appropriate action. The ICRC will also follow this procedure in cases in which the family and physician agree that life-sustaining treatment should be withheld or withdrawn, but the ICRC disagrees.

(iii) *Retrospective record review.* The ICRC, at its regularly-scheduled meeting, will review all records involving withholding or termination of medical or surgical treatment to infants consistent with hospital policies developed by the ICRC, unless the case was previously before the ICRC pursuant to paragraph (f)(3)(ii) of this section. If the ICRC finds that a deviation was made from the institutional policies in a given case, it shall conduct a review and report the findings to appropriate hospital personnel for appropriate action.

(4) *Records.* The ICRC will maintain records of all of its deliberations and summary descriptions of specific cases considered and the disposition of those cases. Such records will be kept in accordance with institutional policies on confidentiality of medical information. They will be made available to appropriate government agencies, or upon court order, or as otherwise required by law.

NOTE: The mandatory provisions set forth in paragraphs (b)—(e) inclusive of this section are subject to an injunction prohibiting their enforcement. In *Bowen* v. *American Hospital Association*, ____ U.S. ____, 106 S. Ct. 2101 (1986), the Supreme Court upheld the action of a United States District Court, 585 F. Supp. 541 (S.D.N.Y. 1984), declaring invalid and enjoining enforcement of provisions under this section, promulgated January 12, 1984.

(Information collection requirements contained in paragraph (c) have been approved by the Office of Management and Budget under control number 0990–0114)

[49 FR 1651, Jan. 12, 1984, as amended at 52 FR 3012, Jan. 30, 1987]

§§ 84.56—84.60 [Reserved]

Subpart G—Procedures

§ 84.61 Procedures.

The procedural provisions applicable to title VI of the Civil Rights Act of 1964 apply to this part. These procedures are found in §§ 80.6 through 80.10 and Part 81 of this Title.

[42 FR 22677, May 4, 1977; 42 FR 22888, May 5, 1977]

APPENDIX A TO PART 84—ANALYSIS OF FINAL REGULATION

SUBPART A—GENERAL PROVISIONS

Definitions—1. *"Recipient".* Section 84.23 contains definitions used throughout the regulation. Most of the comments concerning § 84.3(f), which contains the definition of "recipient," commended the inclusion of recipient whose sole source of Federal financial assistance is Medicaid. The Secretary believes that such Medicaid providers should be regarded as recipients under the statute and the regulation and should be held individually responsible for administering services in a nondiscriminatory fashion. Accordingly, § 84.3(f) has not been changed. Small Medicaid providers, however, are exempt from some of the regulation's administrative provisions (those that apply to recipients with fifteen or more employees). And such recipients will be permitted to refer patients to accessible facilities in certain limited circumstances under revised § 84.22(b). The Secretary recognizes the difficulties involved in Federal enforcement of this regulation with respect to thousands of individual Medicaid providers. As in the case of title VI of the Civil Rights Act of 1964, the Office for Civil Rights will concentrate its compliance efforts on the state Medicaid agencies and will look primarily to them to ensure compliance by individual providers.

One other comment requested that the regulation specify that nonpublic elementary and secondary schools that are not otherwise recipients do not become recipients by virtue of the fact their students participate in certain federally funded programs. The Secretary believes it unnecessary to amend the regulation in this regard, because almost identical language in the Department's regulations implementing title VI and Title IX of the Education Amendments of 1972 has consistently been interpreted so as not to render such schools recipients. These schools, however, are indirectly subject to the substantive requirements of this regulation through the application of § 84.4(b)(iv), which prohibits recipients from assisting agencies that discriminate on the basis of handicap in providing services to beneficiairies of the recipients' programs.

2. *"Federal financial assistance".* In § 84.3(h), defining Federal financial assistance, a clarifying change has been made: procurement contracts are specifically excluded. They are covered, however, by the Department of Labor's regulation under section 503. The Department has never considered such contracts to be contracts of assistance; the explicit exemption has been added only to avoid possible confusion.

The proposed regulation's exemption of contracts of insurance or guaranty has been retained. A number of comments argued for its deletion on the ground that section 504, unlike title VI and title IX, contains no statutory exemption for such contracts. There is no indication, however, in the legislative history of the Rehabilitation Act of 1973 or of the amendments to that Act in 1974, that Congress intended section 504 to have a broader application, in terms of Federal financial assistance, than other civil rights statutes. Indeed, Congress directed that section 504 be implemented in the same manner as titles VI and IX. In view of the long established exemption of contracts of insurance or guaranty under title VI, we think it unlikely that Congress intended section 504 to apply to such contracts.

In its May 1976 Notice of Intent, the Department suggested that the arrangement under which individual practitioners, hospitals, and other facilities receive reimbursement for providing services to beneficiaries under Part B of title XVIII of the Social Security Act (Medicare) constitutes a contract of insurance or guaranty and thus falls within the exemption from the regulation. This explanation oversimplified the Department's view of whether Medicare Part B constitutes Federal financial assistance. The Department's position has consistently been that, whether or not Medicare Part B arrangements involve a contract of insurance or guaranty, no Federal financial assistance flows from the Department to the doctor or other practitioner under the program, since Medicare Part B—like other social security programs—is basically a program of payments to direct beneficiaries.

3. *"Handicapped person"*. Section 84.3(j), which defines the class of persons protected under the regulation, has not been substantially changed. The definition of handicapped person in paragraph (j)(1) conforms to the statutory definition of handicapped person that is applicable to section 504, as set forth in section 111(a) of the Rehabilitation Act Amendments of 1974, Pub. L. 93-516.

The first of the three parts of the statutory and regulatory definition includes any person who has a physical or mental impairment that substantially limits one or more major life activities. Paragraph (j)(2)(i) further defines physical or mental impairments. The definition does not set forth a list of specific diseases and conditions that constitute physical or mental impairments because of the difficulty of ensuring the comprehensiveness of any such list. The term includes, however, such diseases and conditions as orthopedic, visual, speech, and hearing impairments, cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis, cancer, heart disease, diabetes, mental retardation, emotional illness, and, as discussed below, drug addiction and alcoholism.

It should be emphasized that a physical or mental impairment does not constitute a handicap for purposes of section 504 unless its severity is such that it results in a substantial limitation of one or more major life activities. Several comments observed the lack of any definition in the proposed regulation of the phrase "substantially limits." The Department does not believe that a definition of this term is possible at this time.

A related issue raised by several comments is whether the definition of handicapped person is unreasonably broad. Comments suggested narrowing the definition in various ways. the most common recommendation was that only "traditional" handicaps be covered. The Department continues to believe, however, that it has no flexibility within the statutory definition to limit the term to persons who have those severe, permanent, or progressive conditions that are most commonly regarded as handicaps. The Department intends, however, to give particular attention in its enforcement of section 504 to eliminating discrimination against persons with the severe handicaps that were the focus of concern in the Rehabilitation Act of 1973.

The definition of handicapped person also includes specific limitations on what persons are classified as handicapped under the regulation. The first of the three parts of the definition specifies that only physical and mental handicaps are included. Thus, environmental, cultural, and economic disadvantage are not in themselves covered; nor are prison records, age, or homosexuality. Of course, if a person who has any of these characteristics also has a physical or mental handicap, the person is included within the definition of handicapped person.

In paragraph (j)(2)(i), physical or mental impairment is defined to include, among other impairments, specific learning disabilities. The Department will interpret the term as it is used in section 602 of the Education of the Handicapped Act, as amended. Paragraph (15) of section 602 uses the term "specific learning disabilities" to describe such conditions as perceptual handicaps, brain injury, minimal brain dysfunction, dyslexia, and developmental aphasia.

Paragraph (j)(2)(i) has been shortened, but not substantively changed, by the deletion of clause (C), which made explicit the inclusion of any condition which is mental or physical but whose precise nature is not at present known. Clauses (A) and (B) clearly comprehend such conditions.

The second part of the statutory and regulatory definition of handicapped person includes any person who has a record of a physical or mental impairment that substantially limits a major life activity. Under the definition of "record" in paragraph (j)(2)(iii), persons who have a history of a handicapping condition but no longer have the condition, as well as persons who have been incorrectly classified as having such a condition, are protected from discrimination under section 504. Frequently occurring examples of the first group are persons with histories of mental or emotional illness, heart disease, or cancer; of the second group, persons who have been misclassified as mentally retarded.

The third part of the statutory and regulatory definition of handicapped person includes any person who is regarded as having a physical or mental impairment that substantially limits one or more major life activities. It includes many persons who are ordinarily considered to be handicapped but who do not technically fall within the first two parts of the statutory definition, such as persons with a limp. This part of the definition also includes some persons who might not ordinarily be considered handicapped, such as persons with disfiguring scars, as well as persons who have no physical or mental impairment but are treated by a recipient as if they were handicapped.

4. *Drug addicts and alcoholics.* As was the case during the first comment period, the issue of whether to include drug addicts and alcoholics within the definition of handicapped person was of major concern to many commenters. The arguments presented on each side of the issue were similar during the two comment periods, as was the preference of commenters for exclusion of this group of persons. While some comments reflected misconceptions about the implications of including alcoholics and drug addicts within the scope of the regulation, the Secretary understands the concerns that underlie the comments on this question and recognizes that application of section 504 to active alcoholics and drug addicts presents sensitive and difficult questions that must be taken into account in interpretation and enforcement.

The Secretary has carefully examined the issue and has obtained a legal opinion from the Attorney General. That opinion concludes that drug addiction and alcoholism are "physical or mental impairments" within the meaning of section 7(6) of the Rehabilitation Act of 1973, as amended, and that drug addicts and alcoholics are therefore handicapped for purposes of section 504 if their impairment substantially limits one of their major life activities. The Secretary therefore believes that he is without authority to exclude these conditions from the definition. There is a medical and legal consensus that alcoholism and drug addiction are diseases, although there is disagreement as to whether they are primarily mental or physical. In addition, while Congress did not focus specifically on the problems of drug addiction and alcoholism in enacting section 504, the committees that considered the Rehabilitation Act of 1973 were made aware of the Department's long-standing practice of treating addicts and alcoholics as handicapped individuals eligible for rehabilitation services under the Vocational Rehabilitation Act.

The Secretary wishes to reassure recipients that inclusion of addicts and alcoholics within the scope of the regulation will not lead to the consequences feared by many commenters. It cannot be emphasized too strongly that the statute and the regulation apply only to discrimination against qualified handicapped persons solely by reason of their handicap. The fact that drug addiction and alcoholism may be handicaps does not mean that these conditions must be ignored in determining whether an individual is qualified for services or employment opportunities. On the contrary, a recipient may hold a drug addict or alcoholic to the same standard of performance and behavior to which it holds others, even if any unsatisfactory performance or behavior is related to the person's drug addiction or alcoholism. In other words, while an alcoholic or drug addict may not be denied services or disqualified from employment solely because of his or her condition, the behavioral manifestations of the condition may be taken into account in determining whether he or she is qualified.

With respect to the employment of a drug addict or alcoholic, if it can be shown that the addiction or alcoholism prevents successful performance of the job, the person need not be provided the employment opportunity in question. For example, in making employment decisions, a recipient may judge addicts and alcoholics on the same basis it judges all other applicants and employees. Thus, a recipient may consider—for all applicants including drug addicts and alcoholics—past personnel records, absenteeism, disruptive, abusive, or dangerous behavior, violations of rules and unsatisfactory work performance. Moreover, employers may enforce rules prohibiting the possession or use of alcohol or drugs in the workplace, provided that such rules are enforced against all employees.

With respect to services, there is evidence that drug addicts and alcoholics are often denied treatment at hospitals for conditions unrelated to their addiction or alcoholism. In addition, some addicts and alcoholics have been denied emergency treatment. These practices have been specifically prohibited by section 407 of the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1174) and section 321 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (42 U.S.C. 4581), as amended. These statutory provisions are also administered by the Department's Office for Civil Rights and are implemented in § 84.53 of this regulation.

With respect to other services, the implications of coverage, of alcoholics and drug addicts are two-fold: first, no person may be excluded from services solely by reason of the presence or history of these conditions; second, to the extent that the manifestations of the condition prevent the person from meeting the basic eligibility requirements of the program or cause substantial interference with the operation of the program, the condition may be taken into consideration. Thus, a college may not exclude an addict or alcoholic as a student, on the basis of addiction or alcoholism, if the person can successfully participate in the education program and complies with the rules of the college and if his or her behavior does not impede the performance of other students.

Of great concern to many commenters was the question of what effect the inclusion of drug addicts and alcoholics as handicapped persons would have on school disciplinary rules prohibiting the use or possession of drugs or alcohol by students. Neither such rules nor their application to drug addicts or alcoholics is prohibited by this regulation, provided that the rules are enforced evenly with respect to all students.

5. *"Qualified handicapped person."* Paragraph (k) of § 84.3 defines the term "qualified handicapped person." Throughout the regulation, this term is used instead of the statutory term "otherwise qualified handicapped person." The Department believes that the omission of the word "otherwise" is necessary in order to comport with the intent of the statute because, read literally, "otherwise" qualified handicapped persons include persons who are qualified except for their handicap, rather than in spite of their handicap. Under such a literal reading, a blind person possessing all the qualifications for driving a bus except sight could be said to be "otherwise qualified" for the job of driving. Clearly, such a result was not intended by Congress. In all other respects, the terms "qualified" and "otherwise qualified" are intended to be interchangeable.

Section 84.3(k)(1) defines a qualified handicapped person with respect to employment as a handicapped person who can, with reasonable accommodation, perform the essential functions of the job in question. The term "essential functions" does not appear in the corresponding provision of the Department of Labor's section 503 regulation, and a few commenters objected to its inclusion on the ground that a handicapped person should be able to perform all job tasks. However, the Department believes that inclusion of the phrase is useful in emphasizing that handicapped persons should not be disqualified simply because they may have difficulty in performing tasks that bear only a marginal relationship to a particular job. Further, we are convinced that inclusion of the phrase is not inconsistent with the Department of Labor's application of its definition.

Certain commenters urged that the definition of qualified handicapped person be amended so as explicitly to place upon the employer the burden of showing that a particular mental or physical characteristic is essential. Because the same result is achieved by the requirement contained in paragraph (a) of § 84.13, which requires an employer to establish that any selection criterion that tends to screen out handicapped persons is job-related, that recommendation has not been followed.

Section 84.3(k)(2) (formerly § 84.3(k)(3)) defines qualified handicapped person, with respect to preschool, elementary, and secondary programs, in terms of age. Several commenters recommended that eligibility for the services be based upon the standard of substantial benefit, rather than age, because of the need of many handicapped children for early or extended services if they are to have an equal opportunity to benefit from education programs. No change has been made in this provision, again because of the extreme difficulties in administration that would result from the choice of the former standard. Under the remedial action provisions of § 84.6(a)(3), however, persons beyond the age limits prescribed in § 84.3(k)(2) may in appropriate cases be required to be provided services that they were formerly denied because of a recipient's violation of section 504.

Section 84.3(k)(2) states that a handicapped person is qualified for preschool, elementary, or secondary services if the person is of an age at which nonhandicapped persons are eligible for such services or at which state law mandates the provision of educational services to handicapped persons. In addition, the extended age ranges for which recipients must provide full educational opportunity to all handicapped persons in order to be eligible for assistance under the Education of the Handicapped Act—generally, 3-18 as of September 1978, and 3-21 as of September 1980 are incorporated by reference in this paragraph.

Section 84.3(k)(3) formerly § 84.3(k)(2)) defines qualified handicapped person with respect to postsecondary educational programs. As revised, the paragraph means that both academic and technical standards must be met by applicants to these programs. The term "technical standards" refers to all nonacademic admissions criteria that are essential to participation in the program in question.

6. *General prohibitions against discrimination.* Section 84.4 contains general prohibitions against discrimination applicable to all recipients of assistance from this Department.

Paragraph (b)(1(i) prohibits the exclusion of qualified handicapped persons from aids, benefits, or services, and paragraph (ii) requires that equal opportunity to participate or benefit be provided. Paragraph (iii) requires that services provided to handicapped persons be as effective as those provided to the nonhandicapped. In paragraph (iv), different or separate services are prohibited except when necessary to provide equally effective benefits.

In this context, the term "equally effective," defined in paragraph (b)(2), is intended to encompass the concept of equivalent, as opposed to identical, services and to acknowledge the fact that in order to meet the individual needs of handicapped persons to the same extent that the corresponding needs of nonhandicapped persons are met, adjustments to regular programs or the provision of different programs may sometimes be necessary. For example, a welfare office that uses the telephone for communicating with its clients must provide alternative modes of communicating with its deaf clients. This standard parallels the one established under title VI of Civil Rights Act of 1964 with respect to the provision of educational services to students whose primary language is not English. See *Lau* v. *Nichols*, 414 U.S. 563 (1974). To be equally effective, however, an aid, benefit, or service need not produce equal results; it merely must afford an equal opportunity to achieve equal results.

It must be emphasized that, although separate services must be required in some instances, the provision of unnecessarily separate or different services is discriminatory. The addition to paragraph (b)(2) of the phrase "in the most integrated setting appropriated to the person's needs" is intended to reinforce this general concept. A new paragraph (b)(3) has also been added to § 84.4, requiring recipients to give qualified handicapped persons the option of participating in regular programs despite the existence of permissibly separate or different programs. The requirement has been reiterated in §§ 84.38 and 84.47 in connection with physical education and athletics programs.

Section 84.4(b)(1)(v) prohibits a recipient from supporting another entity or person that subjects participants or employees in the recipient's program to discrimination on the basis of handicap. This section would, for example, prohibit financial support by a recipient to a community recreational group or to a professional or social organization that discriminates against handicapped persons. Among the criteria to be considered in each case are the substantiality of the relationship between the recipient and the other entity, including financial support by the recipient, and whether the other entity's activities relate so closely to the recipient's program or activity that they fairly should be considered activities of the recipient itself. Paragraph (b)(1)(vi) was added in response to comment in order to make explicit the prohibition against denying qualified handicapped persons the opportunity to serve on planning and advisory boards responsible for guiding federally assisted programs or activities.

Several comments appeared to interpret § 84.4(b)(5), which proscribes discriminatory site selection, to prohibit a recipient that is located on hilly terrain from erecting any new buildings at its present site. That, of course, is not the case. This paragraph is not intended to apply to construction of additional buildings at an existing site. Of course, any such facilities must be made accessible in accordance with the requirements of § 84.23.

7. *Assurances of compliance.* Section 84.5(a) requires a recipient to submit to the Director an assurance that each of its programs and activities receiving or benefiting from Federal financial assistance from this Department will be conducted in compliance with this regulation. To facilitate the submission of assurances by thousands of Medicaid providers, the Department will follow the title VI procedures of accepting, in lieu of assurances, certification on Medicaid vouchers. Many commenters also sought relief from the paperwork requirements imposed by the Department's enforcement of its various civil rights responsibilities by requesting the Department to issue one form incorporating title VI, title IX, and section 504 assurances. The Secretary is sympathetic to this request. While it is not feasible to adopt a single civil rights assurance form at this time, the Office for Civil Rights will work toward that goal.

8. *Private rights of action.* Several comments urged that the regulation incorporate provision granting beneficiaries a private right of action against recipients under section 504. To confer such a right is beyond the authority of the executive branch of Government. There is, however, case law holding that such a right exists. *Lloyd* v. *Regional Transportation Authority*, 548 F. 2d 1277 (7th Cir. 1977); *see Hairston* v. *Drosick*, Civil No. 75-0691 (S.D. W. Va., Jan. 14, 1976); *Gurmankin* v. *Costanzo*, 411 F. Supp. 982 (E.D. Pa. 1976); *cf. Lau* v. *Nichols*, *supra*.

9. *Remedial action.* Where there has been a finding of discrimination, § 84.6 requires a recipient to take remedial action to overcome the effects of the discrimination. Actions that might be required under paragraph (a)(1) include provision of services to persons previously discriminated against, reinstatement of employees and development of a remedial action plan. Should a recipient fail to take required remedial action, the ultimate sanctions of court action or termination of Federal financial assistance may be imposed.

Paragraph (a)(2) extends the responsibility for taking remedial action to a recipient that exercises control over a noncomplying recipient. Paragraph (a)(3) also makes clear that handicapped persons who are not in the program at the time that remedial action is required to be taken may also be the subject of such remedial action. This paragraph has been revised in response to comments in order to include persons who would have been in the program if discriminatory practices had not existed. Paragraphs (a) (1), (2), and (3) have also been amended in response to comments to make plain that, in appropriate cases, remedial action might be required to redress clear violations of the statute itself that occurred before the effective date of this regulation.

10. *Voluntary action.* In § 84.6(b), the term "voluntary action" has been substituted for the term "affirmative action" because the use of the latter term led to some confusion. We believe the term "voluntary action" more accurately reflects the purpose of the paragraph. This provision allows action, beyond that required by the regulation, to overcome conditions that led to limited participation by handicapped persons, whether or not the limited participation was caused by any discriminatory actions on the part of the recipient. Several commenters urged that paragraphs (a) and (b) be revised to require remedial action to overcome effects of prior discriminatory practices regardless of whether there has been an express finding of discrimination. The self-evaluation requirement in paragraph (c) accomplishes much the same purpose.

11. *Self-evaluation.* Paragraph (c) requires recipients to conduct a self-evaluation in order to determine whether their policies or practices may discriminate against handicapped persons and to take steps to modify any discriminatory policies and practices and their effects. The Department received many comments approving of the addition to paragraph (c) of a requirement that recipients seek the assistance of handicapped persons in the self-evaluation process. This paragraph has been further amended to require consultation with handicapped persons or organizations representing them before recipients undertake the policy modifications and remedial steps prescribed in paragraphs (c) (1)(ii) and (iii).

Paragraph (c)(2), which sets forth the recordkeeping requirements concerning self-evaluation, now applies only to recipients with fifteen or more employees. This change was made as part of an effort to reduce unnecessary or counterproductive administrative obligations on small recipients. For those recipients required to keep records, the requirements have been made more specific; records must include a list of persons consulted and a description of areas examined, problems identified, and corrective steps taken. Moreover, the records must be made available for public inspection.

12. *Grievance procedure.* Section 84.7 (formerly § 84.8) requires recipients with fifteen or more employees to designate an individual responsible for coordinating its compliance efforts and to adopt a grievance procedure. Two changes were made in the section in response to comment. A general requirement that appropriate due process procedures be followed has been added. It was decided that the details of such procedures could not at this time be specified because of the varied nature of the persons and entities who must establish the procedures and of the programs to which they apply. A sentence was also added to make clear that grievance procedures are not required to be made available to unsuccessful applicants for employment or to applicants for admission to colleges and universities.

The regulation does not require that grievance procedures be exhausted before recourse is sought from the Department. However, the Secretary believes that it is desirable and efficient in many cases for complainants to seek resolution of their complaints and disputes at the local level and therefore encourages them to use available grievance procedures.

A number of comments asked whether compliance with this section or the notice requirements of § 84.8 could be coordinated with comparable action required by the title IX regulation. The Department encourages such efforts.

13. *Notice.* Section 84.8 (formerly § 84.9) sets forth requirements for dissemination of statements of nondicrimination policy by recipients.

It is important that both handicapped persons and the public at large be aware of the obligations of recipients under section 504. Both the Department and recipients have responsibilities in this regard. Indeed the Department intends to undertake a major public information effort to inform persons of their rights under section 504 and this regulation. In § 84.8 the Department has sought to impose a clear obligation on major recipients to notify beneficiaries and employees of the requirements of section 504, without dictating the precise way in which this notice must be given. At the same time, we have avoided imposing requirements on small recipients (those with fewer than fifteen employees) that would create unnecessary and counterproductive paper work burdens on them and unduly stretch the enforcement resources of the Department.

Section 84.8(a), as simplified, requires recipients with fifteen or more employees to take appropriate steps to notify beneficiaries and employees of the recipient's obligations under section 504. The last sentence of § 84.8(a) has been revised to list possible, rather than required, means of notification. Section 84.8(b) requires recipients to include a notification of their policy of nondiscrimination in recruitment and other general information materials.

In response to a number of comments, § 84.8 has been revised to delete the requirements of publication in local newspapers, which has proved to be both troublesome and ineffective. Several commenters suggested that notification on separate forms be allowed until present stocks of publications and forms are depleted. The final regulation explicitly allows this method of compliance. The separate form should, however, be included with each significant publication or form that is distributed.

Former § 84.9(b)(2), which prohibited the use of materials that might give the impression that a recipient excludes qualified handicapped persons from its program, has been deleted. The Department is convinced by the comments that this provision is unnecessary and difficult to apply. The Department encourages recipients, however, to include in their recuitment and other general information materials photographs of handicapped persons and ramps and other features of accessible buildings.

Under new § 84.9 the Director may, under certain circumstances, require recipients with fewer than fifteen employees to comply with one or more of these requirements. Thus, if experience shows a need for imposing notice or other requirements on particular recipients or classes of small recipients, the Department is prepared to expand the coverage of these sections.

14. *Inconsistent State laws.* Section 84.10(a) states that compliance with the regulation is not excused by state or local laws limiting the eligibility of qualified handicapped persons to receive services or to practice an occupation. The provision thus applies only with respect to state or local laws that unjustifiably differentiate on the basis of handicap.

Paragraph (b) further points out that the presence of limited employment opportunities in a particular profession, does not excuse a recipient from complying with the regulation. Thus, a law school could not deny admission to a blind applicant because blind laywers may find it more difficult to find jobs that do nonhandicapped lawyers.

SUBPART B—EMPLOYMENT PRACTICES

Subpart B prescribes requirements for nondiscrimination in the employment practices of recipients of Federal financial assistance administered by the Department. This subpart is consistent with the employment provisions of the Department's regulation implementing title IX of the Education Amendments of 1972 (45 CFR Part 86) and the regulation of the Department of Labor under section 503 of the Rehabilitation Act, which requries certain Federal contractors to take affirmative action in the employment and advancement of qualified handicapped persons. All recipients subject to title IX are also subject to this regulation. In addition, many recipients subject to this regulation receive Federal procurement contracts in excess of $2,500 and are therefore also subject to section 503.

15. *Discriminatory practices.* Section 84.11 sets forth general provisions with respect to discrimination in employment. A new paragraph (a)(2) has been added to clarify the employment obligations of recipients that receive Federal funds under Part B of the Education of the Handicapped Act, as amended (EHA). Section 606 of the EHA obligates elementary or secondary school systems that receive EHA funds to take positive steps to employ and advance in employment qualified handicapped persons. This obligation is similar to the nondiscrimination requirement of section 504 but requires recipients to take additional steps to hire and promote handicapped persons. In enacting section 606 Congress chose the words "positive steps" instead of "affirmative action" advisedly and did not intend section 606 to incorporate the types of activities required under Executive Order 11246 (affirmative action on the basis of race, color, sex, or national origin) or under sections 501 and 503 of the Rehabilitation Act of 1973.

Paragraph (b) of § 84.11 sets forth the specific aspects of employment covered by the regulation. Paragraph (c) provides that inconsistent provisions of collective bargaining agreements do not excuse noncompliance.

16. *Reasonable accommodation.* The reasonable accommodation requirement of § 84.12 generated a substantial number of comments. The Department remains convinced that its approach is both fair and effective. Moreover, the Department of Labor reports that it has experienced little difficulty in administering the requirements of reasonable accommodation. The provision therefore remains basically unchanged from the proposed regulation.

Section 84.12 requires a recipient to make reasonable accommodation to the known physical or mental limitations of a handicapped applicant or employee unless the recipient can demonstrate that the accommodation would impose an undue hardship on the operation of its program. Where a handicapped person is not qualified to perform a particular job, where reasonable accommodation does not overcome the effects of a person's handicap, or where reasonable accommodation causes undue hardship to the employer, failure to hire or promote the handicapped person will not be considered discrimination.

Section 84.12(b) lists some of the actions that constitute reasonable accommodation. The list is neither all-inclusive nor meant to suggest that employers must follow all of the actions listed.

Reasonable accommodation includes modification of work schedules, including part-time employment, and job restructuring. Job restructuring may entail shifting nonessential duties to other employees. In other cases, reasonable accommodation may include physical modifications or relocation of particular offices or jobs so that they are in facilities or parts of facilities that are accessible to and usable by handicapped persons. If such accommodations would cause undue hardship to the employer, they need not be made.

Paragraph (c) of this section sets forth the factors that the Office for Civil Rights will consider in determining whether an accommodation necessary to enable an applicant or employee to perform the duties of a job would impose an undue hardship. The weight given to each of these factors in making the determination as to whether an accommodation constitutes undue hardship will vary depending on the facts of a particular situation. Thus, a small day-care center might not be required to expend more than a nominal sum, such as that necessary to equip a telephone for use by a secretary with impaired hearing, but a large school district might be required to make available a teacher's aide to a blind applicant for a teaching job. Further, it might be considered reasonable to require a state welfare agency to accommodate a deaf employee by providing an interpreter, while it would constitute an undue hardship to impose that requirement on a provider of foster home care services. The reasonable accommodation standard in § 84.12 is similar to the obligation imposed upon Federal contractors in the regulation implementing section 503 of the Rehabilitation Act of 1973, administered by the Department of Labor. Although the wording of the reasonable accommodation provisions of the two regulations is not identical, the obligation that the two regulations impose is the same, and the Federal Government's policy in implementing the two sections will be uniform. The Department adopted the factors listed in paragraph (c) instead of the "business necessity" standard of the Labor regulation because that term seemed inappropriate to the nature of the programs operated by the majority of institutions subject to this regulation, e.g., public school systems, hospitals, colleges and universities, nursing homes, day-care centers, and welfare offices. The factors listed in paragraph (c) are intended to make the rationale underlying the business necessity standard applicable to an understandable by recipients of HHS funds.

17. *Tests and selection criteria.* Revised § 84.13(a) prohibits employers from using test or other selection criteria that screen out or tend to screen out handicapped persons unless the test or criterion is shown to be job-related and alternative tests or criteria that do not screen out or tend to screen out as many handicapped persons are not shown by the Director to be available. This paragraph is an application of the principle established under title VII of the Civil Rights Act of 1964 in *Griggs* v. *Duke Power Company*, 401 U.S. 424 (1971).

Under the proposed section, a statistical showing of adverse impact on handicapped persons was required to trigger an employer's obligation to show that employment criteria and qualifications relating to handicap were necessary. This requirement was changed because the small number of handicapped persons taking tests would make statistical showings of "disproportionate, adverse effect" difficult and burdensome. Under the altered, more workable provision, once it is shown that an employment test substantially limits the opportunities of handicapped persons, the employer must show the test to be job-related. A recipient is no longer limited to using predictive validity studies as the method for demonstrating that a test or other selection criterion is in fact job-related. Nor, in all cases, are predictive validity studies sufficient to demonstrate that a test or criterion is job-related. In addition, § 84.13(a) has been revised to place the burden on the Director, rather than the recipient, to identify alternate tests.

Section 84.13(b) requires that a recipient take into account that some tests and criteria depend upon sensory, manual, or speaking skills that may not themselves be necessary to the job in question but that may make the handicapped person unable to pass the test. The recipient must select and administer tests so as best to ensure that the test will measure the handicapped person's ability to perform on the job rather than the person's ability to see, hear, speak, or perform manual tasks, except, of course, where such skills are the factors that the test purports to measure. For example, a person with a speech impediment may be perfectly qualified for jobs that do not or need not, with reasonable accommodation, require ability to speak clearly. Yet, if given an oral test, the person will be unable to perform in a satisfactory manner. The test results will not, therefore, predict job performance but instead will reflect impaired speech.

18. *Preemployment inquiries.* Section 84.14, concerning preemployment inquiries, generated a large number of comments. Commenters representing handicapped persons strongly favored a ban on preemployment inquiries on the ground that such inquiries are often used to discriminate against handicapped persons and are not necessary to serve any legitimate interests of employers. Some recipients, on the other hand, argued that preemployment inquiries are necessary to determine qualifications of the applicant, safety hazards caused by a

particular handicapping condition, and accommodations that might required.

The Secretary has concluded that a general prohibition of preemployment inquiries is appropriate. However, a sentence has been added to paragraph (a) to make clear that an employer may inquire into an applicant's ability to perform job-related tasks but may not ask if the person has a handicap. For example, an employer may not ask on an employment form if an applicant is visually impaired but may ask if the person has a current driver's license (if that is a necessary qualification for the position in question). Similarly, employers may make inquiries about an applicant's ability to perform a job safely. Thus, an employer may not ask if an applicant is an epileptic but may ask whether the person can perform a particular job without endangering other employees.

Section 84.14(B) allows preemployment inquiries only if they are made in conjunction with required remedial action to correct past discrimination, with voluntary action to overcome past conditions that have limited the participation of handicapped persons, or with obligations under section 503 of the Rehabilitation Act of 1973. In these instances, paragraph (b) specifies certain safeguards that must be followed by the employer.

Finally, the revised provision allows an employer to condition offers of employment to handicapped persons on the results of medical examinations, so long as the examinations are administered to all employees in a nondiscriminatory manner and the results are treated on a confidential basis.

19. *Specific acts of Discrimination.* Sections 84.15 (recruitment), 84.16 (compensation), 84.17 (job classification and structure) and 84.18 (fringe benefits) have been deleted from the regulation as unnecessarily duplicative of § 84.11 (discrimination prohibited). The deletion of these sections in no way changes the substantive obligations of employers subject to this regulation from those set forth in the July 16 proposed regulation. These deletions bring the regulation closer in form to the Department of Labor's section 503 regulation.

Proposed § 84.18, concerning fringe benefits, had allowed for differences in benefits or contributions between handicapped and nonhandicapped persons in situations only where such differences could be justified on an actuarial basis. Section 84.11 simply bars discrimination in providing fringe benefits and does not address the issue of actuarial differences. The Department believes that currently available data and experience do not demonstrate a basis for promulgating a regulation specifically allowing for differences in benefits or contributions.

SUBPART C—PROGRAM ACCESSIBILITY

In general, Subpart C prohibits the exclusion of qualified handicapped persons from federally assisted programs or activities because a recipient's facilities are inaccessible or unusable.

20. *Existing facilities.* Section 84.22 maintains the same standard for nondiscrimination in regard to existing facilities as was included in the proposed regulation. The section states that a recipients program or activity, when viewed in its entirety, must be readily accessible to and usable by handicapped persons. Paragraphs (a) and (b) make clear that a recipient is not required to make each of its existing facilities accessible to handicapped persons if its program as a whole is accessible. Accessibility to the recipient's program or activity may be achieved by a number of means, including redesign of equipment, reassignment of classes or other services to accessible buildings, and making aides available to beneficiaries. In choosing among methods of compliance, recipients are required to give priority consideration to methods that will be consistent with provision of services in the most appropriate integrated setting. Structural changes in existing facilities are required only where there is no other feasible way to make the recipient's program accessible.

Under § 84.22, a university does not have to make all of its existing classroom buildings accessible to handicapped students if some of its buildings are already accessible and if it is possible to reschedule or relocate enough classes so as to offer all required courses and a reasonable selection of elective courses in accessible facilities. If sufficient relocation of classes is not possible using existing facilities, enough alterations to ensure program accessibility are required. A university may not exclude a handicapped student from a specifically requested course offering because it is not offered in an accessible location, but it need not make every section of that course accessible.

Commenters representing several institutions of higher education have suggested that it would be appropriate for one postsecondary institution in a geographical area to be made accessible to handicapped persons and for other colleges and universities in that area to participate in that school's program, thereby developing an educational consortium for the postsecondary education of handicapped students. The Department believes that such a consortium, when developed and applied only to handicapped persons, would not constitute compliance with § 84.22, but would discriminate against qualified handicapped persons by restricting their choice in selecting institutions of higher education and would, therefore, be inconsistent with the basic objectives of the statute.

Nothing in this regulation, however, should be read as prohibiting institutions from forming consortia for the benefit of all students. Thus, if three colleges decide that it would be cost-efficient for one college to offer biology, the second physics, and the third chemistry to all students at the three colleges, the arrangement would not violate section 504. On the other hand, it would violate the regulation if the same institutions set up a consortium under which one college undertook to make its biology lab accessible, another its physics lab, and a third its chemistry lab, and under which mobility-impaired handicapped students (but not other students) were required to attend the particular college that is accessible for the desired courses.

Similarly, while a public school district need not make each of its buildings completely accessible, it may not make only one facility or part of a facility accessible if the result is to segregate handicapped students in a single setting.

All recipients that proivde health, welfare, or other social services may also comply with § 84.22 by delivering services at alternate accessible sites or making home visits. Thus, for example, a pharmacist might arrange to make home deliveries of drugs. Under revised § 84.22(c), small providers of health, welfare, and social services (those with fewer than fifteen employees) may refer a beneficiary to an accessible provider of the desired service, but only if no means of meeting the program accessibility requirement other than a significant alteration in existing facilties is available. The referring recipient has the responsibility of determining that the other provider is in fact accessible and willing to provide the service. The Secretary believes this "last resort" referral provision is appropriate to avoid imposition of additional costs in the health care area, to encourage providers to remain in the Medicaid program, and to avoid imposing significant costs on small, low-budget providers such as day-care centers or foster homes.

A recent change in the tax law may assist some recipients in meeting their obligations under this section. Under section 2122 of the Tax Reform Act of 1976, recipients that pay federal income tax are eligible to claim a tax deduction of up to $25,000 for architectural and transportation modifications made to improve accessibility for handicapped persons. Many physicians and dentists, among others, may be eligible for this tax deduction. See 42 FR 17870 (April 4, 1977), adopting 26 CFR 7.190.

Several commenters expressed concern about the feasibility of compliance with the program accessibility standard. The Secretary believes that the standard is flexible enough to permit recipients to devise ways to make their programs accessible short of extremely expensive or impractical physical changes in facilities. Accordingly, the section does not allow for waivers. The Department is ready at all times to provide technical assistance to recipients in meeting their program accessibility responsibilities. For this purpose, the Department is establishing a special technical assistance unit. Recipients are encouraged to call upon the unit staff for advice and guidance both on structural modifications and on other ways of meeting the program accessibility requirement.

Paragraph (d) has been amended to require recipients to make all nonstructural adjustments necessary for meeting the program accessibility standard within sixty days. Only where structural changes in facilities are necessary will a recipient be permitted up to three years to accomplish program accessibility. It should be emphasized that the three-year time period is not a waiting period and that all changes must be accomplished as expeditiously as possible. Further, it is the Department's belief, after consultation with experts in the field, that outside ramps to buildings can be constructed quickly and at relatively low cost. Therefore, it will be expected that such structural additions will be made promptly to comply with § 84.22(d).

The regulation continues to provide, as did the proposed version, that a recipient planning to achieve program accessibility by making structural changes must develop a transition plan for such changes within six months of the effective date of the regulation. A number of commenters suggested extending that period to one year. The secretary believes that such an extension is unnecessary and unwise. Planning for any necessary structural changes should be undertaken promptly to ensure that they can be completed within the three-year period. The elements of the transition plan as required by the regulation remain virtually unchanged from the proposal but § 84.22(d) now includes a requirement that the recipient make the plan available for public inspection.

Several commenters expressed concern that the program accessibility standard would result in the segregation of handicapped persons in educational institutions. The regulation will not be applied to permit such a result. See § 84.4(c)(2)(iv), prohibiting unnecessarily separate treatment; § 84.35, requiring that students in elementary and secondary schools be educated in the most integrated setting appropriate to their needs; and new § 84.43(d), applying the same standard to postsecondary education.

We have received some comments from organizations of handicapped persons on the subject of requiring, over an extended period of time, a barrier-free environment—that is, requiring the removal of all architectural barriers in existing facilities. The Department has considered these comments but has decided to take no further action at this time concerning these suggestions, believing that such action should only be considered in light of experience in implementing the program accessibility standard.

21. *New construction.* Section 84.23 requires that all new facilities, as well as alterations that could affect access to and use of existing facilities, be designed and constructed in a manner so as to make the facility accessible to and usable by handicapped persons. Section 84.23(a) has been amended so that it applies to each newly constructed facility if the construction was commenced after the effective date of the regulation. The words "if construction has commenced" will be considered to mean "if groundbreaking has takenplace." Thus, a recipient will not be required to alter the design of a facility that has progressed beyond groundbreaking prior to the effective date of the regulation.

Paragraph (b) requires certain alterations to conform to the requirement of physical accessibility in paragraph (a). If an alteration is undertaken to a portion of a building the accessibility of which could be improved by the manner in which the alteration is carried out, the alteration must be made in that manner. Thus, if a doorway or wall is being altered, the door or other wall opening must be made wide enough to accommodate wheelchairs. On the other hand, if the alteration consists of altering ceilings, the provisions of this section are not applicable because this alteration cannot be done in a way that affects the accessibility of that portion of the building. The phrase "to the maximum extent feasible" has been added to allow for the occasional case in which the nature of an existing facility is such as to make it impractical or prohibitively expensive to renovate the building in a manner that results in its being entirely barrier-free. In all such cases, however, the alteration should provide the maximum amount of physical accessibility feasible.

As proposed, § 84.23(c) required compliance with the American National Standards Institute (ANSI) standard on building accessibility as the minimum necessary for compliance with the accessibility requirement of § 84.23 (a) and (b). The regerence to the ANSI standard created some ambiguity, since the standard itself provides for waivers where other methods are equally effective in providing accessibility to the facility. Moreover, the Secretary does not wish to discourage innovation in barrier-free construction by requiring absolute adherence to a rigid design standard. Accordingly, § 84.23 (c) has been revised to permit departures from particular requirements of the ANSI standard where the recipient can demonstrate that equivalent access to the facility is provided.

Section 84.23(d) of the proposed regulation, providing for a limited deferral of action concerning facilities that are subject to section 502 as well as section 504 of the Act, has been deleted. The Secretary believes that the provision is unnecessary and inappropriate to this regulation. The Department will, however, seek to coordinate enforcement activities under this regulation with those of the Architectural and Transportation Barriers Compliance Board.

SUBPART D—PRESCHOOL, ELEMENTARY, AND SECONDARY EDUCATION

Subpart D sets forth requirements for nondiscrimination in preschool, elementary, secondary, and adult education programs and activities, including secondary vocational education programs. In this context, the term "adult education" refers only to those educational programs and activities for adults that are operated by elementary and secondary schools.

The provisions of Subpart D apply to state and local educational agencies. Although the subpart applies, in general, to both public and private education programs and activities that are federally assisted, §§ 84.32 and 84.33 apply only to public programs and § 84.39 applies only to private programs; §§ 84.35 and 84.36 apply both to public programs and to those private programs that include special services for handicapped students.

Subpart B generally conforms to the standards established for the education of handicapped persons in *Mills* v. *Board of Education of the District of Columbia*, 348 F. Supp. 866 (D.D.C. 1972), *Pennsylvania Association for Retarded Children* v. *Commonwealth of Pennsylvania*, 344 F. Supp. 1257 (E.D. 1971), 343 F. Supp. 279 (E.D. Pa. 1972), and *Lebanks* v. *Spears*, 60, F.R.D. 135 (E.D. La. 1973), as well as in the Education of the Handicapped Act, as amended by Pub. L. 94-142 (the EHA).

The basic requirements common to those cases, to the EHA, and to this regulation are (1) that handicapped persons, regardless of the nature or severity of their handicap, be provided a free appropriate public education, (2) that handicapped students be educated with nonhandicapped students to the maximum extent appropriate to their needs, (3) that educational agencies undertake to identify and locate all unserved handicapped children, (4) that evaluation procedures be improved in order to avoid the inappropriate education that results from the misclassification of students, and (5) that procedural safeguard be established to enable parents and guardians to influence decisions regarding the evaluation and placement of their children. These requirements are designed to ensure that no handicapped child is excluded from school on the basis of handicap and, if a recipient demonstrates that placement in a regular educational setting cannot be achieved satisfactorily, that the student is provided with adequate alternative services suited to the student's needs without additional cost to the student's parents or guardian. Thus, a recipient that operates a public school system must either educate handicapped children in its regular program or provide such children with an appropriate alternative education at public expense.

It is not the intention of the Department, except in extraordinary circumstances, to review the result of individual placement and other educational decisions, so long as the school district complies with the "process" requirements of this subpart (concerning identification and location, evaluation, and due process procedures). However, the Department will place a high priority on investigating cases which may involve exclusion of a child from the education system or a pattern or practice of discriminatory placements or education.

22. *Location and notification.* Section 84.32 requires public schools to take steps annually to identify and locate handicapped children who are not receiving an education and to publicize to handicapped children and their parents the rights and duties established by section 504 and this regulation. This section has been shortened without substantive change.

23. *Free appropriate public education.* Former §§ 84.34 ("Free education") and 84.36(a) ("Suitable education") have been consolidated and revised in new § 84.33. Under § 84.34(a), a recipient is responsible for providing a free appropriate public education to each qualified handicapped person who is in the recipient's jurisdiction. The word "in" encompasses the concepts of both domicile and actual residence. If a recipient places a child in a program other than its own, it remains financially responsible for the child, whether or not the other program is operated by another recipient or educational agency. Moreover, a recipient may not place a child in a program that is inappropriate or that otherwise violates the requirements of Subpart D. And in no case may a recipient refuse to provide services to a handicapped child in its jurisdiction because of another person's or entity's failure to assume financial responsibility.

Section 84.33(b) concerns the provision of appropriate educational services to handicapped children. To be appropriate, such services must be designed to meet handicapped children's individual educational needs to the same extent that those of nonhandicapped children are met. An appropriate education could consist of education in regular classes, education in regular classes with the use of supplementary services, or special education and related services. Special education may include specially designed instruction in classrooms, at home, or in private or public institutions and may be accompanied by such related services as developmental, corrective, and other supportive services (including psychological, counseling, and medical diagnostic services). The placement of the child must however, be consistent with the requirements of § 84.34 and be suited to his or her educational needs.

The quality of the educational services provided to handicapped students must equal that of the services provided to nonhandicapped students; thus, handicapped student's teachers must be trained in the instruction of persons with the handicap in question and appropriate materials and equipment must be available. The Department is aware that the supply of adequately trained teachers may, at least at the outset of the imposition of this requirement, be insufficient to meet the demand of all recipients. This factor will be considered in determining the appropriateness of the remedy for noncompliance with this section. A new § 84.33(b)(2) has been added, which allows this requirement to be met through the full implementation of an individualized education program developed in accordance with the standards of the EHA.

Paragraph (c) of § 84.33 sets forth the specific financial obligations of a recipient. If a recipient does not itself provide handicapped persons with the requisite services, it must assume the cost of any alternate placement. If, however, a recipient offers adequate services and if alternate placement is chosen by a student's parent or guardian, the recipient need not assume the cost of the outside services. (If the parent or guardian believes that his or her child cannot be suitably educated in the recipient's program, he or she may make use of the procedures established in § 84.36.) Under this paragraph, a recipient's obligation extends beyond the provision of tuition payments in the case of placement outside the regular program. Adequate transportation must also be provided. Recipients must also pay for psychological services and those medical services necessary for diagnostic and evaluative purposes.

If the recipient places a student, because of his or her handicap, in a program that necessitates his or her being away from home, the payments must also cover room and board and nonmedical care (including custodial and supervisory care). When residential care is necessitated not by the student's handicap but by factors such as the student's home conditions, the recipient is not required to pay the cost of room and board.

Two new sentences have been added to paragraph (c)(1) to make clear that a recipient's financial obligations need not be met solely through its own funds. Recipients may rely on funds from any public or private source including insurers and similar third parties.

The EHA requires a free appropriate education to be provided to handicapped children "no later than September 1, 1978," but section 504 contains no authority for delaying enforcement. To resolve this problem, a new paragraph (d) has been added to § 84.33. Section 84.33(d) requires recipients to achieve full compliance with the free appropriate public education requirements of § 84.33 as expeditiously as possible, but in no event later than September 1, 1978. The provision also makes clear that, as of the effective date of this regulation, no recipient may exclude a qualified handicapped child from its educational program. This provision against exclusion is consistent with the order of providing services set forth in section 612(3) of the EHA, which places the highest priority on providing services to handicapped children who are not receiving an education.

24. *Educational setting.* Section 84.34 prescribes standards for educating handicapped persons with nonhandicapped persons to the maximum extent appropriate to the needs of the handicapped person in question. A handicapped student may be removed from the regular educational setting only where the recipient can show that the needs of the student would, on balance, be served by placement in another setting.

Although under § 84.34, the needs of the handicapped person are determinative as to proper placement, it should be stressed that, where a handicapped student is so disruptive in a regular classroom that the education of other students is significantly impaired, the needs of the handicapped child cannot be met in that environment. Therefore, regular placement would not be appropriate to his or her needs and would not be required by § 84.34.

Among the factors to be considered in placing a child is the need to place the child as close to home as possible. A new sentence has been added to paragraph (a) requiring recipients to take this factor into account. As pointed out in several comments, the parents' right under § 84.36 to challenge the placement of their child extends not only to placement in special classes or separate schools but also to placement in a distant school and, in particular, to residential placement. An equally appropriate educational program may exist closer to home; this issue may be raised by the parent or guardian under §§ 84.34 and 84.36.

New paragraph (b) specified that handicapped children must also be provided nonacademic services in as integrated a setting as possible. This requirement is especially important for children whose educational needs necessitate their being solely with other handicapped children during most of each day. To the maximum extent appropriate, children in residential settings are also to be provided opportunities for participation with other children.

Section 84.34(c) (formerly § 84.38) requires that any facilities that are identifiable as being for handicapped students be comparable in quality to other facilities of the recipient. A number of comments objected to this section on the basis that it encourages the creation and maintenance of such facilities. This is not the intent of the provision. A separate facility violates section 504 unless it is indeed necessary to the provision of an appropriate education to certain handicapped students. In those instances in which such facilities are necessary (as might be the case, for example, for severely retarded persons), this provision requires that the educational services provided be comparable to those provided in the facilities of the recipient that are not identifiable as being for handicapped persons.

25. *Evaluation and placement.* Because the failure to provide handicapped persons with an appropriate education is so frequently the result of misclassification or misplacement, § 84.33(b)(1) makes compliance with its provisions contingent upon adherence to certain procedures designed to ensure appropriate classification and placement. These procedures, delineated in §§ 84.35 and 84.36, are concerned with testing and other evaluation methods and with procedural due process rights.

Section 84.35(a) requires that an individual evaluation be conducted before any action is taken with respect either to the initial placement of a handicapped child in a regular or special education program or to any subsequent significant change in that placement. Thus, a full reevaluation is not required every time an adjustment in placement is made. "Any action" includes denials of placement.

Paragraphs (b) and (c) of § 84.35 establishes procedures designed to ensure that children are not misclassified, unnecessarily labeled as being handicapped, or incorrectly placed because of inappropriate selection, administration, or interpretation of evaluation materials. This problem has been extensively documented in "Issues in the Classification of, Children," a report by the Project on Classification of Exceptional Children, in which the HHS Interagency Task Force participated. The provisions of these paragraphs are aimed primarily at abuses in the placement process that result from misuse of, or undue or misplaced reliance on, standardized scholastic aptitude tests.

Paragraph (b) has been shortened but not substantively changed. The requirement in former subparagraph (1) that recipients provide and administer evaluation materials in the native language of the student has been deleted as unnecessary, since the same requirement already exists under title VI and is more appropriately covered under that statute. Subparagraphs (1) and (2) are, in general, intended to prevent misinterpretation and similar misuse of test scores and, in particular, to avoid undue reliance on general intelligence tests. Subparagraph (3) requires a recipient to administer tests to a student with impaired sensory, manual, or speaking skills in whatever manner is necessary to avoid distortion of the test results by the impairment. Former subparagraph (4) has been deleted as unnecessarily repetitive of the other provisions of this paragraph.

Paragraph (c) requires a recipient to draw upon a variety of sources in the evaluation process so that the possibility of error in classification is minimized. In particular, it requires that all significant factors relating to the learning process, including adaptive behavior, be considered. (Adaptive behavior is the effectiveness with which the individual meets the standards of personal independence and social responsibility expected of his or her age and cultural group.) Information from all sources must be documented and considered by a group of persons, and the procedure must ensure that the child is placed in the most integrated setting appropriate.

The proposed regulation would have required a complete individual reevaluation of the student each year. The Department has concluded that it is inappropriate in the section 504 regulation to require full reevaluations on such a rigid schedule. Accordingly, § 84.35(c) requires periodic reevaluations and specifies that reevaluations in accordance with the EHA will constitute compliance. The proposed regulation implementing the EHA allows reevaluation at three-year intervals except under certain specified circumstances.

Under § 84.36, a recipient must establish a system of due process procedures to be afforded to parents or guardians before the recipient takes any action regarding the identification, evaluation, or educational placement of a person who, because of handicap, needs or is believed to need special education or related services. This section has been revised. Because the due process procedures of the EHA, incorporated by reference in the proposed section 504 regulation, are inappropriate for some recipients not subject to that Act, the section now specifies minimum necessary procedures: notice, a right to inspect records, an impartial hearing with a right to representation by counsel, and a review procedure. The EHA procedures remain one means of meeting the regulation's due process requirements, however, and are recommended to recipients as a model.

26. *Nonacademic services.* Section 84.37 requires a recipient to provide nonacademic and extracurricular services and activities in such manner as is necessary to afford handicapped students an equal opportunity for participation. Because these services and activities are part of a recipient's education program, they must, in accordance with the provisions of § 84.34, be provided in the most integrated setting appropriate.

Revised paragraph (c)(2) does permit separation or differentiation with respect to the provision of physical education and athletics activities, but only if qualified handicapped students are also allowed the opportunity to compete for regular teams or participate in regular activities. Most handicapped students are able to participate in one or more regular physical education and athletics activities. For example, a student in a wheelchair can participate in regular archery course, as can a deaf student in a wrestling course.

Finally, the one-year transition period provided in former § 84.37(a)(3) was deleted in response to the almost unanimous objection of commenters to that provision.

27. *Preschool and adult education.* Section 84.38 prohibits discrimination on the basis of handicap in preschool and adult education programs. Former paragraph (b), which emphasized that compensatory programs for disadvantaged children are subject to section 504, has been deleted as unnecessary, since it is comprehended by paragraph (a).

28. *Private education.* Section 84.39 sets forth the requirements applicable to recipients that operate private education programs and activities. The obligations of these recipients have been changed in two significant respects: first, private schools are subject to the evaluation and due process provisions of the subpart only if they operate special education programs; second, under § 84.39(b), they may charge more for providing services to handicapped students than to nonhandicapped students to the extent that additional charges can be justified by increased costs.

Paragraph (a) of § 84.39 is intended to make clear that recipients that operate private education programs and activities are not required to provide an appropriate education to handicapped students with special educational needs if the recipient does not offer programs designed to meet those needs. Thus, a private school that has no program for mentally retarded persons is neither required to admit such a person into its program nor to arrange or pay for the provision of the person's education in another program. A private recipient without a special program for blind students, however, would not be permitted to exclude, on the basis of blindness, a blind applicant who is able to participate in the regular program with minor adjustments in the manner in which the program is normally offered.

SUBPART E—POSTSECONDARY EDUCATION

Subpart E prescribes requirements for nondiscrimination in recruitment, admission, and treatment of students in postsecondary education programs and activities, including vocational education.

29. *Admission and recruitment.* In addition to a general prohibition of discrimination on the basis of handicap in § 84.42(a), the regulation delineates, in § 84.42(b), specific prohibitions concerning the establishment of limitations on admission of handicapped students, the use of tests or selection criteria, and preadmission inquiry. Several changes have been made in this provision.

Section 84.42(b) provides that postsecondary educational institutions may not use any test or criterion for admission that has a disproportionate, adverse effect on handicapped persons unless it has been validated as a predictor of academic success and alternate tests or criteria with a less disproportionate, adverse effect are shown by the Department to be available. There are two significant changes in this approach from the July 16 proposed regulation.

First, many commenters expressed concern that § 84.42(b)(2)(ii) could be interpreted to require a "global search" for alternate tests that do not have a disproportionate, adverse impact on handicapped persons. this was not the intent of the provision and, therefore, it has been amended to place the burden on the Director of the Office for Civil Rights, rather than on the recipient, to identify alternate tests.

Second, a new paragraph (d), concerning validity studies, has been added. Under the proposed regulation, overall success in an education program, not just first-year grades, was the criterion against which admissions tests were to be validated. This approach has been changed to reflect the comment of professional testing services that use of first year grades would be less disruptive of present practice and that periodic validity studies against overall success in the education program. would be sufficient check on the reliability of first-year grades.

Section 84.42(b)(3) also requires a recipient to assure itself that admissions tests are selected and administered to applicants with impaired sensory, manual, or speaking skills in such manner as is necessary to avoid unfair distortion of test results. Methods have been developed for testing the aptitude and achievement of persons who are not able to take written tests or even to make the marks required for mechanically scored objective tests; in addition, methods for testing persons with visual or hearing impairments are available. A recipient, under this paragraph, must assure itself that such methods are used with respect to the selection and administration of any admissions tests that it uses.

Section 84.42(b)(3)(iii) has been amended to require that admissions tests be administered in facilities that, on the whole, are accessible. In this context, "on the whole" means that not all of the facilities need be accessibile so long as a sufficient number of facilities are available to handicapped persons.

Revised § 84.42(b)(4) generally prohibits preadmission inquiries as to whether an applicant has a handicap. The considerations that led to this revision are similar to those underlying the comparable revision of § 84.14 on preemployment inquiries. The regulation does, however, allow inquiries to be made, after admission but before enrollment, as to handicaps that may require accommodation.

New paragraph (c) parallels the section on preemployment inquiries and allows postsecondary institutions to inquire about applicants' handicaps before admission, subject to certain safeguards, if the purpose of the inquiry is to take remedial action to correct past discrimination or to take voluntary action to overcome the limited participation of handicapped persons in postsecondary educational institutions.

Proposed § 84.42(c), which would have allowed different admissions criteria in certain cases for handicapped persons, was widely misinterpreted in comments from both handicapped persons and recipients. We have concluded that the section is unnecessary, and it has been deleted.

30. *Treatment of students.* Section 84.43 contains general provisions prohibiting the discriminatory treatment of qualified handicapped applicants. Paragraph (b) requires recipients to ensure that equal opportunities are provided to its handicapped students in education programs and activities that are not operated by the recipient. The recipient must be satisfied that the outside education program or activity as a whole is nondiscriminatory. For example, a college must ensure that discrimination on the basis of handicap does not occur in connection with teaching assignments of student teachers in elementary or secondary schools not operated by the college. Under the "as a whole" wording, the college could continue to use elementary or secondary school systems that discriminate if, and only if, the college's student teaching program, when viewed in its entirety, offered handicapped student teachers the same range and quality

of choice in student teaching assignments afforded nonhandicapped students.

Paragraph (c) of this section prohibits a recipient from excluding qualified handicapped students from any course, course of study, or other part of its education program or activity. This paragraph is designed to eliminate the practice of excluding handicapped persons from specific courses and from areas of concentration because of factors such as ambulatory difficulties of the student or assumptions by the recipient that no job would be available in the area in question for a person with that handicap.

New paragraph (d) requires postsecondary institutions to operate their programs and activities so that handicapped students are provided services in the most integrated setting appropriate. Thus, if a college had several elementary physics classes and had moved one such class to the first floor of the science building to accommodate students in wheelchairs, it would be a violation of this paragraph for the college to concentrate handicapped students with no mobility impairments in the same class.

31. *Academic adjustments.* Paragraph (a) of § 84.44 requires that a recipient make certain adjustments to academic requirements and practices that discriminate or have the effect of discriminating on the basis of handicap. This requirement, like its predecessor in the proposed regulation, does not obligate an institution to waive course or other academic requirements. But such institutions must accommodate those requirements to the needs of individual handicapped students. For example, an institution might permit an otherwise qualified handicapped student who is deaf to substitute an art appreciation or music history course for a required course in music appreciation or could modify the manner in which the music appreciation course is conducted for the deaf student. It shoud be stressed that academic requirements that can be demonstrated by the recipient to be essential to its program of instruction or to particular degrees need not be changed.

Paragraph (b) provides that postsecondary institutions may not impose rules that have the effect of limiting the participation of handicapped students in the education program. Such rules include prohibition of tape recorders or braillers in classrooms and dog guides in campus buildings. Several recipients expressed concern about allowing students to tape record lectures because the professor may later want to copyright the lectures. This problem may be solved by requiring students to sign agreements that they will not release the tape recording or transcription or otherwise hinder the professor's ability to obtain a copyright.

Paragraph (c) of this section, concerning the administration of course examinations to students with impaired sensory, manual, or speaking skills, parallels the regulation's provisions on admissions testing (§ 84.42(b)) and will be similarly interpreted.

Under § 84.44(d), a recipient must ensure that no handicapped student is subject to discrimination in the recipient's program because of the absence of necessary auxiliary educational aids. Colleges and universities expressed concern about the costs of compliance with this provision.

The Department emphasizes that recipients can usually meet this obligation by assisting students in using existing resources for auxiliary aids such as state vocational rehabilitation agencies and private charitable organizations. Indeed, the Department anticipates that the bulk of auxiliary aids will be paid for by state and private agencies, not by colleges or universities. In those circumstances where the recipient institution must provide the educational auxiliary aid, the institution has flexibility in choosing the methods by which the aids will be supplied. For example, some universities have used students to work with the institution's handicapped students. Other institutions have used existing private agencies that tape texts for handicapped students free of charge in order to reduce the number of readers needed for visually impaired students.

As long as no handicapped person is excluded from a program because of the lack of an appropriate aid, the recipient need not have all such aids on hand at all times. Thus, readers need not be available in the recipient's library at all times so long as the schedule of times when a reader is available is established, is adhered to, and is sufficient. Of course, recipients are not required to maintain a complete braille library.

32. *Housing.* Section 84.45(a) requires postsecondary institutions to provide housing to handicapped students at the same cost as they provide it to other students and in a convenient, accessible, and comparable manner. Commenters, particularly blind persons pointed out that some handicapped persons can live in any college housing and need not wait to the end of the transition period in Subpart C to be offered the same variety and scope of housing accommodations given to nonhandicapped persons. The Department concurs with this position and will interpret this section accordingly.

A number of colleges and universities reacted negatively to paragraph (b) of this section. It provides that, if a recipient assists in making off-campus housing available to its students, it should develop and implement procedures to assure itself that off-campus housing, as a whole, is available to handicapped students. Since postsecondary institutions are presently required to assure themselves that off-campus housing is provided in a manner that does not discriminate on the basis of sex (§ 86.32 of the title IX regulation), they may use the procedures developed under title IX in order to comply with § 84.45(b). It should be emphasized that not every off-campus living accommodation need be made accessible to handicapped persons.

33. *Health and insurance.* Section 84.46 of the proposed regulation, providing that recipients may not discriminate on the basis of handicap in the provision of health related services, has been deleted as duplicative of the general provisions of § 84.43. This deletion represents no change in the obligation of recipients to provide nondiscriminatory health and insurance plans. The Department will continue to require that nondiscriminatory health services be provided to handicapped students. Recipients are not required, however, to provide specialized services and aids to handicapped persons in health programs. If, for example, a college infirmary treats only simple disorders such as cuts, bruises, and colds, its obligation to handicapped persons is to treat such disorders for them.

34. *Financial assistance.* Section 84.46(a) (formerly § 84.47), prohibiting discrimination in providing financial assistance, remains substantively the same. It provides that recipients may not provide less assistance to or limit the eligibility of qualified handicapped persons for such assistance, whether the assistance is provided directly by the recipient or by another entity through the recipient's sponsorship. Awards that are made under wills, trusts, or similar legal instruments in a discriminatory manner are permissible, but only if the overall effect of the recipient's provision of financial assistance is not discriminatory on the basis of handicap.

It will not be considered discriminatory to deny, on the basis of handicap, an athletic scholarship to a handicapped person if the handicap renders the person unable to qualify for the award. For example, a student who has a neurological disorder might be denied a varsity football scholarship on the basis of his inability to play football, but a deaf person could not, on the basis of handicap, be denied a scholarship for the school's diving team. The deaf person could, however, be denied a scholarship on the basis of comparative diving ability.

Commenters on § 84.46(b), which applies to assistance in obtaining outside employment for students, expressed similar concerns to those raised under § 84.43(b), concerning cooperative programs. This paragraph has been changed in the same manner as § 84.43(b) to include the "as a whole" concept and will be interpreted in the same manner as § 84.43(b).

35. *Nonacademic services.* Section 84.47 (formerly § 84.48) establishes nondiscrimination standards for physical education and athletics counseling and placement services, and social organizations. This section sets the same standards as does § 84.38 of Subpart D, discussed above, and will be interpreted in a similar fashion.

SUBPART F—HEALTH, WELFARE, AND SOCIAL SERVICES

Subpart F applies to recipients that operate health, welfare, and social service programs. The Department received fewer comments on this subpart than on others.

Although many commented that Subpart F lacked specificity, these commenters provided neither concrete suggestions nor additions. Nevertheless, some changes have been made, pursuant to comment, to clarify the obligations of recipients in specific areas. In addition, in an effort to reduce duplication in the regulation, the section governing recipients providing health services (proposed § 84.52) has been consolidated with the section regulating providers of welfare and social services (proposed § 84.53). Since the separate provisions that appeared in the proposed regulation were almost identical, no substantive change should be inferred from their consolidation.

Several commenters asked whether Subpart F applies to vocational rehabilitation agencies whose purpose is to assist in the rehabilitation of handicapped persons. To the extent that such agencies receive financial assistance from the Department, they are covered by Subpart F and all other relevant subparts of the regulation. Nothing in this regulation, however, precludes such agencies from servicing only handicapped persons. Indeed, § 84.4(c) permits recipients to offer services or benefits that are limited by federal law to handicapped persons or classes of handicapped persons.

Many comments suggested requiring state health, welfare, and social service agencies to take an active role in the enforcement of section 504 with regard to local health and social service providers. The Department believes that the possibility for federal-state cooperation in the administration and enforcement of section 504 warrants further consideration. Moreover, the Department will rely largely on state Medicaid agencies, as it has under title VI, for monitoring compliance by individual Medicaid providers.

A number of comments also discussed whether section 504 should be read to require payment of compensation to institutionalized handicapped patients who perform services for the institution in which they reside. The Department of Labor has recently issued a proposed regulation under the Fair Labor Standards Act (FLSA) that covers the question of compensation for institutionalized persons. 42 FR 15224 (March 18, 1977). This Department will seek information and comment from the Department of Labor concerning that agency's experience administering the FLSA regulation.

36. *Health, welfare, and other social service providers.* As already noted, § 84.53 has been combined with proposed § 84.53 into a single section covering health, welfare, and other social services. Section 84.52(a) has been expanded in several respects. The addition of new paragraph (a)(2) is intended to make clear the basic requirement of equal opportunity to receive benefits or services in the health, welfare, and social service areas. The paragraph parallels §§ 84.4(b)(ii) and 84.43(b). New paragaph (a)(3) requires the provision of effective benefits or services, as defined in § 84.4(b)(2) (i.e., benefits or services which "afford handicapped persons equal opportunity to obtain the same result (or) to gain the same benefit * * *").

Section 84.52(a) also includes provisions concerning the limitation of benefits or services to handicapped persons and the subjection of handicapped persons to different eligibility standards. (These provisions were previously included in the welfare recipient section (§ 84.53(a)).) One common misconception about the regulation is that it would require specialized hospitals and other health care providers to treat all handicapped persons. The regulation makes no such requirement. Thus, a burn treatment center need not provide other types of medical treatment to handicapped persons unless it provides such medical services to nonhandicapped persons. It could not, however, refuse to treat the burns of a deaf person because of his or her deafness.

Commenters had raised the question of whether the prohibition against different standards of eligibility might preclude recipients from providing special services to handicapped persons or classes of handicapped persons. The regulation will not be so interpreted, and the specific section in question has been eliminated. Section 84.4(c) makes clear that special programs for handicapped persons are permitted.

A new paragraph (a)(5) concerning the provision of different or separate services or benefits has been added. This provision prohibits such treatment unless necessary to provide qualified handicapped persons with benefits and services that are as effective as those provided to others.

Section 84.52(a)(2) of the proposed regulation has been omitted as duplicative of revised § 84.22 (b) and (c) in Subpart C. As discussed above, these sections permit health care providers to arrange to meet patients in accessible facilities and to make referrals in carefully limited circumstances.

Section 84.52(a)(3) of the proposed regulation has been redesignated § 84.52(b) and has been amended to cover written material concerning waivers of rights or consent to treatment as well as general notices concerning health benefits or services. The section requires the recipient to ensure that qualified handicapped persons are not denied effective notice because of their handicap. For example, recipients could use several different types of notice in order to reach persons with impaired vision or hearing, such as brailled messages, radio spots, and tacticle devices on cards or envelopes to inform blind persons of the need to call the recipient for further information.

Sections 84.52(a)(4), 84.52(a)(5), and 84.52(b) have been omitted from the regulation as unnecessary. They are clearly comprehended by the more general sections banning discrimination.

Section 84.52(c) is a new section requiring recipient hospitals to establish a procedure for effective communication with persons with impaired hearing for the purpose of providing emergency health care. Although it would be appropriate for a hospital to fulfill its responsibilities under this section by having a full-time interpreter for the deaf on staff, there may be other means of accomplishing the desired result of assuring that some means of communication is immediately available for deaf persons needing emergency treatment.

Section 84.52(d), also a new provision, requires recipients with fifteen or more employees to provide appropriate auxiliary aids for persons with impaired sensory, manual, or speaking skills. Further, the Director may require a small provider to furnish auxiliary aids where the provision of aids would not adversely affect the ability of the recipient to provide its health benefits or service. Thus although a small nonprofit neighborhood clinic might not be obligated to have available an interpreter for deaf persons, the Director may require provision of such aids as may be reasonably available to ensure that qualified handicapped persons are not denied appropriate benefits or services because of their handicaps.

37. *Treatment of Drug Addicts and Alcoholics.* Section 84.53 is a new section that prohibits discrimination in the treatment and admission of drug and alcohol addicts to hospitals and outpatient facilities. This section is included pursuant to section 407, Pub. L. 92—255, the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1174), as amended, and section 321, Pub. L. 91-616, the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4581), as amended, and section 321, Pub. L. 93-282. Section 504 itself also prohibits such discriminatory treatment and, in addition, prohibits similar discriminatory treatment by other types of health providers. Section 84.53 prohibits discrimination against drug abusers by operators of outpatient facilities, despite the fact that section 407 pertains

only to hospitals, because of the broader application of section 504. This provision does not mean that all hospitals and outpatient facilities must treat drug addiction and alcoholism. It simply means, for example, that a cancer clinic may not refuse to treat cancer patients simply because they are also alcoholics.

38. *Education of institutionalized persons.* The regulation retains § 84.54 of the proposed regulation that requires that an appropriate education be provided to qualified handicapped persons who are confined to residential institutions or day care centers.

SUBPART C—PROCEDURES

In § 84.61, the Secretary has adopted the title VI complaint and enforcement procedures for use in implementing section 504 until such time as they are superseded by the issuance of a consolidated procedureal regulation applicable to all of the civil rights statutes and executive orders administered by the Department.

APPENDIX B TO PART 84—GUIDELINES FOR ELIMINATING DISCRIMINATION AND DENIAL OF SERVICES ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, SEX, AND HANDICAP IN VOCATIONAL EDUCATION PROGRAMS

EDITORIAL NOTE: For the text of these guidelines, see 45 CFR Part 80, Appendix B.

[44 FR 17168, Mar. 21, 1979]

APPENDIX C TO PART 84—GUIDELINES RELATING TO HEALTH CARE FOR HANDICAPPED INFANTS

(a) *Interpretative guidelines relating to the applicability of this part to health care for handicapped infants.* The following are interpretative guidelines of the Department set forth here to assist recipients and the public in understanding the Department's interpretation of section 504 and the regulations contained in this part as applied to matters concerning health care for handicapped infants. These interpretative guidelines are illustrative; they do not independently establish rules of conduct.

(1) With respect to programs and activities receiving Federal financial assistance, health care providers may not, solely on the basis of present or anticipated physical or mental impairments of an infant, withhold treatment or nourishment from the infant who, in spite of such impairments, will medically benefit from the treatment or nourishment.

(2) Futile treatment or treatment that will do no more than temporarily prolong the act of dying of a terminally ill infant is not considered treatment that will medically benefit the infant.

(3) In determining whether certain possible treatments will be medically beneficial to an infant, reasonable medical judgments in selecting among alternative courses of treatment will be respected.

(4) Section 504 and the provisions of this part are not applicable to parents (who are not recipients of Federal financial assistance). However, each recipient health care provider must in all aspects of its health care programs receiving Federal financial assistance provide health care and related services in a manner consistent with the requirements of section 504 and this part. Such aspects includes decisions on whether to report, as required by State law or otherwise, to the appropriate child protective services agency a suspected instance of medical neglect of a child, or to take other action to seek review or parental decisions to withhold consent for medically indicated treatment. Whenever parents make a decision to withhold consent for medically beneficial treatment or nourishment, such recipient providers may not, solely on the basis of the infant's present or anticipated future mental or physical impairments, fail to follow applicable procedures on reporting such incidents to the child protective services agency or to seek judicial review.

(5) The following are examples of applying these interpretative guidelines. These examples are stated in the context of decisions made by recipient health care providers. Were these decisions made by parents, the guideline stated in section (a)(4) would apply. These examples assume no facts or complications other than those stated. Because every case must be examined on its individual facts, these are merely illustrative examples to assist in understanding the framework for applying the nondiscrimination requirements of section 504 and this part.

(i) Withholding of medically beneficial surgery to correct an intestinal obstruction in an infant with Down's Syndrome when the withholding is based upon the anticipated future mental retardation of the infant and there are no medical contraindications to the surgery that would otherwise justify withholding the surgery would constitute a discriminatory act, violative of section 504.

(ii) Withholding of treatment for medically correctable physical anomalies in children born with spina bifida when such denial is based on anticipated mental impairment paralysis or incontinence of the infant, rather than on reasonable medical judgments that treatment would be futile, too unlikely of success given complications in the particular case, or otherwise not of medical benefit to the infant, would constitute a discriminatory act, violative of section 504.

(iii) Withholding of medical treatment for an infant born with anencephaly, who will inevitably die within a short period of time, would not constitute a discriminatory act because the treatment would be futile and do no more than temporarily prolong the act of dying.

(iv) Withholding of certain potential treatments from a severely premature and low birth weight infant on the grounds of reasonable medical judgments concerning the improbability of success or risks of potential harm to the infant would not violate section 504.

(b) *Guidelines for HHS investigations relating to health care for handicapped infants.* The following are guidelines of the Department in conducting investigations relating to health care for handicapped infants. They are set forth here to assist recipients and the public in understanding applicable investigative procedures. These guidelines do not establish rules of conduct, create or affect legally enforceable rights of any person, or modify existing rights, authorities or responsibilities pursuant to this part. These guidelines reflect the Department's recognition of the special circumstances presented in connection with complaints of suspected life-threatening noncompliance with this part involving health care for handicapped infants. These guidelines do not apply to other investigations pursuant to this part, or other civil rights statutes and rules. Deviations from these guidelines may occur when, in the judgment of the responsible Department official, other action is necessary to protect the life or health of a handicapped infant.

(1) Unless impracticable, whenever the Department receives a complaint of suspected life-threatening noncompliance with this part in connection with health care for a handicapped infant in a program or activity receiving Federal financial assistar[illegible] HHS will immediately conduct a prelim[illegible] inquiry into the matter by initiat[illegible]ele-phone contact with the recipient ho[illegible] to obtain information relating to the co[illegible]ion and treatment of the infant who is the subject of the complaint. The preliminary inquiry, which may include additional contact with the complainant and a requirement that pertinent records be provided to the Department, will generally be completed within 24 hours (or sooner if indicated) after receipt of the complaint.

(2) Unless impracticable, whenever a recipient hospital has an Infant Care Review Committee, established and operated substantially in accordance with the provisions of 45 CFR 84.55(f), the Department will, as part of its preliminary inquiry, solicit the information available to, and the analysis and recomendations of, the ICRC. Unless, in the judgment of the responsible Department official, other action is necessary to protect the life or health of a handicapped infant, prior to initiating an on-site investigation, the Department will await receipt of this information from the ICRC for 24 hours (or less if indicated) after receipt of the complaint. The Department may require a subsequent written report of the ICRC's findings, accompanied by pertinent records and documentation.

(3) On the basis of the information obtained during preliminary inquiry, including information provided by the hospital (including the hospital's ICRC, if any), information provided by the complainant, and all other information obtained, the Department will determine whether there is a need for an on-site investigation of the complaint. Whenever the Department determines that doubt remains that the recipient hospital or some other recipient is in compliance with this part or additional documentation is desired to substantiate a conclusion, the Department will initiate an on-site investigation or take some other appropriate action. Unless impracticable, prior to initiating an on-site investigation, the Department's medical consultant (referred to in paragraph 6) will contact the hospital's ICRC or appropriate medical personnel of the recipient hospital.

(4) In conducting on-site investigations, when a recipient hospital has an ICRC established and operated substantially in accordance with the provisions of 45 CFR 84.55(f), the investigation will begin with, or include at the earliest practicable time, a meeting with the ICRC or its designees. In all on-site investigations, the Department will make every effort to minimize any potential inconvenience or disruption, accommodate the schedules of health care professionals and avoid making medical records unavailable. The Department will also seek to coordinate its investigation with any related investigations by the state child protective services agency so as to minimize potential disruption.

(5) It is the policy of the Department to make no comment to the public or media regarding the substance of a pending preliminary inquiry or investigation.

(6) The Department will obtain the assistance of a qualified medical consultant to evaluate the medical information (including medical records) obtained in the course of a preliminary inquiry or investigation. The name, title and telephone number of the Department's medical consultant will be made available to the recipient hospital. The Department's medical consultant will, if appropriate, contact medical personnel of the recipient hospital in connection with the preliminary inquiry, investigation or medical consultant's evaluation. To the

extent practicable, the medical consultant will be a specialist with respect to the condition of the infant who is the subject of the preliminary inquiry or investigation. The medical consultant may be an employee of the Department or another person who has agreed to serve, with or without compensation, in that capacity.

(7) The Department will advise the recipient hospital of its conclusions as soon as possible following the completion of a preliminary inquiry or investigation. Whenever final administrative findings following an investigation of a complaint of suspected life-threatening noncompliance cannot be made promptly, the Department will seek to notify the recipient and the complainant of the Department's decision on whether the matter will be immediately referred to the Department of Justice pursuant to 45 CFR 80.8

(8) Except as necessary to determine or effect compliance, the Department will (i) in conducting preliminary inquiries and investigations, permit information provided by the recipient hospital to the Department to be furnished without names or other identifying information relating to the infant and the infant's family; and (ii) to the extent permitted by law, safeguard the confidentiality of information obtained.

[49 FR 1653, Jan. 12, 1984]

PART 85—ENFORCEMENT OF NONDISCRIMINATION ON THE BASIS OF HANDICAP IN PROGRAMS OR ACTIVITIES CONDUCTED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

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AUTHORITY: 29 U.S.C. 794.

SOURCE: 53 FR 25603, July 8, 1988, unless otherwise noted.

EDITORIAL NOTE: At the request of the Department of Health and Human Services, the "Section-by-Section Analysis" portion of the preamble of the document published at 53 FR 25595, July 8, 1988, as corrected at 53 FR 26559, July 13, 1988, appears at the end of Part 85.

§ 85.1 Purpose.

The purpose of this part is to effectuate section 119 of the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978, which amended section 504 of the Rehabilitation Act of 1973 to prohibit discrimination on the basis of handicap in programs or activities conducted by Executive agencies or the United States Postal Service.

§ 85.2 Application.

This part applies to all programs or activities conducted by the agency, except for programs or activities conducted outside the United States that do not involve individuals with handicaps in the United States.

§ 85.3 Definitions.

For purposes of this part, the term—

"Agency" means the Department of Health and Human Services or any component part of the Department of Health and Human Services that conducts a program or activity covered by this part. "Component agency" means such component part.

"Assistant Attorney General" means the Assistant Attorney General, Civil Rights Division, United States Department of Justice.

"Auxiliary aids" means services or devices that enable persons with impaired sensory, manual, or speaking skills to have an equal opportunity to participate in, and enjoy the benefits of, programs or activities conducted by the agency. For example, auxiliary aids useful for persons with impaired vision include readers, Brailled materials, audio recordings, and other similar services and devices. Auxiliary aids useful for persons with impaired hearing include telephone handset amplifiers, telephones compatible with hearing aids, telecommunication devices for deaf persons (TDD's) interpreters, notetakers, written materials, and other similar services and devices.

"Complete complaint" means a written statement that contains the complainant's name and address and describes the agency's alleged discriminatory action in sufficient detail to inform the agency of the nature and date of the alleged violation of section 504. It shall be signed by the complainant or by someone authorized to do so on his or her behalf. Complaints filed on behalf of classes or third parties shall describe or identify (by name, if possible) the alleged victims of discrimination.

"Facility" means all or any portion of buildings, structures, equipment, roads, walks, parking lots, rolling stock or other conveyances, or other real or personal property.

"Individual with Handicaps" means any person who has a physical or mental impairment that substantially limits one or more major life activities, has a record of such an impairment, or is regarded as having such an impairment. As used in this definition, the phrase:

(1) "Physical or mental impairment" includes

(i) Any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems: neurological; musculoskeletal; special sense organs; respiratory, including speech organs; cardiovascular; reproductive; digestive; genito-urinary; hemic and lymphatic; skin; and endocrine; or

(ii) Any mental or psychological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities. The term "physical or mental impairment" includes, but is not limited to, such diseases and conditions as orthopedic, visual, speech and hearing impairments, cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis, cancer, heart disease, diabetes, mental retardation, emotional illness, and drug addiction and alcoholism.

(2) "Major life activities" includes functions such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning and working.

(3) "Has a record of such impairment" means has a history of, or is misclassified as having, a mental or physical impairment that substantially limits one or more major life activities.

(4) "Is regarded as having an impairment" means:

(i) Has a physical or mental impairment that does not substantially limit major life activities but is treated by the agency as constituting such a limitation.

(ii) Has a physical or mental impairment that substantially limits major life activities only as a result of the attitudes of others toward such impairment; or

(iii) Has none of the impairments defined in paragraph (1) of this definition but is treated by the agency as having such an impairment.

"OCR" means the Office for Civil Rights of the Department of Health and Human Services.

"OCR Director/Special Assistant" means the Director of the Office for Civil Rights, who serves concurrently as the Special Assistant to the Secretary for Civil Rights, or a designee of the Director/Special Assistant.

"Qualified individual with handicaps" means:

(1) With respect to preschool, elementary, or secondary education services provided by the agency, an individual with handicaps who is a member of a class of persons otherwise entitled by statute, regulation, or agency policy to receive educational services from the agency;

(2) With respect to any other agency program or activity under which a person is required to perform services or to achieve a particular level of accomplishment, an individual with handicaps who meets the essential eligibility requirements and who can achieve the purpose of the program or activity without modifications in the program or activity that the agency can demonstrate would result in a fundamental alteration in its nature; and

(3) With respect to any other program or activity, an individual with handicaps who meets the essential eligibility requirements for participation in, or receipt of benefits from, that program or activity; and

(4) "Qualified handicapped person" as that term is defined for purposes of employment in 29 CFR 1613.702(f), which is made applicable to this part by §85.31.

"Secretary" means the Secretary of the Department of Health and Human Services or his/her designee.

"Section 504" means section 504 of the Rehabilitation Act of 1973 (Pub. L. 93-112, 87 Stat. 394 (29 U.S.C. 794)), as amended by the Rehabilitation Act Amendments of 1974 (Pub. L. 93-516, 88 Stat. 1617); the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978 (Pub. L. 95-602, 92 Stat. 2955); the Rehabilitation Act Amendments of 1986 (Pub. L 99-566, 100 Stat. 1810); and the Civil Rights Restoration Act of 1987 (Pub. L. 100-259, 102 Stat. 28). As used in this part, section 504 applies only to programs or activities conducted by the agency and not to federally assisted programs.

§§ 85.4—85.10 [Reserved]

§ 85.11 Self-evaluation.

(a) The agency shall, within one year of the effective date of this part, evaluate its current policies and practices, and the effects thereof, that do not or may not meet the requirements of this part, and, to the extent modification of any such policies and practices is required, the agency shall proceed to make the necessary modifications. Any new operating or staff divisions established within the agency shall have one year from the date of their establishment to carry out this evaluation.

(b) The agency shall provide an opportunity to interested persons, including individuals with handicaps or organizations representing individuals with handicaps, to participate in the self-evaluation by submitting comments (both oral and written).

(c) The agency shall, for at least three years following completion of the self-evaluation, maintain on file and make available for public inspection and copying—

(1) A description of areas examined and any problems identified; and

(2) A description of any modifications made.

§ 85.12 Notice.

The agency shall make available to employees, applicants, participants, beneficiaries, and other interested persons such information regarding the provisions of this part and its applicability to the programs or activities conducted by the agency, and make such information available to them in such a manner as the agency head finds necessary to apprise such persons of the protections against discrimination assured them by section 504 and this part.

§§ 85.13—85.20 [Reserved]

§ 85.21 General prohibitions against discrimination.

(a) No qualified individual with handicaps shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity conducted by the agency.

(b) (1) The agency, in providing any aid, benefit, or service, may not, directly or through contractual, licensing, or other arrangements, on the basis of handicap—

(i) Deny a qualified individual with handicaps the opportunity to participate in or benefit from the aid, benefit, or service;

(ii) Afford a qualified individual with handicaps an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded others;

(iii) Provide a qualified individual with handicaps with an aid, benefit, or service that is not as effective in affording equal opportunity to obtain the same result, to gain the same benefit, or to reach the same level of achievement as that provided to others;

(iv) Provide different or separate aids, benefits, or services to individuals with handicaps or to any class or individuals with handicaps than is provided to others unless such action is necessary to provide qualified individuals with handicaps with aids, benefits or services that are as effective as those provided to others;

(v) Deny a qualified individual with handicaps the opportunity to participate as a member of a planning or advisory board; or

(vi) Otherwise limit a qualified individual with handicaps in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving the aid, benefit, or service.

(2) The agency may not deny a qualified individual with handicaps the opportunity to participate in programs or activities that are not separate or different, despite the existence of permissibly separate or different programs or activities.

(3) The agency may not, directly or through contractual or other arrangements, utilize criteria or methods of administration the purpose or effect of which would—

(i) Subject qualified individuals with handicaps to discrimination on the basis of handicap; or

(ii) Defeat or substantially impair accomplishment of the objectives of a program or activity with respect to individuals with handicaps.

(4) The agency may not, in determining the site or location of a facility, make selections the purpose or effect of which would—

(i) Exclude individuals with handicaps from, deny them the benefits of, or otherwise subject them to discrimination under any program or activity conducted by the agency; or

(ii) Defeat or substantially impair the accomplishment of the objectives of a program or activity with respect to individuals with handicaps.

(5) The agency, in the selection of procurement contractors, may not use criteria that subject qualified individuals with handicaps to discrimination on the basis of handicap.

(6) The agency may not administer a licensing or certification program in a manner that subjects qualified individuals with handicaps to discrimination on the basis of handicap, nor may the agency establish requirements for the programs or activities of licensees or certified entities that subject qualified individuals with handicaps to discrimination on the basis of handicap. However, the programs or activities of entities that are licensed or certified by the agency are not, themselves, covered by this part.

(c) The exclusion of individuals without handicaps from the benefits of a program limited by Federal statute or Executive order to individuals with handicaps or the exclusion of a specific class of individuals with handicaps from a program limited by Federal statute or Executive order to a different class of individuals with handicaps is not prohibited by this part.

(d) The agency shall administer programs and activities in the most integrated setting appropriate to the needs of qualified individuals with handicaps.

§§ 85.22—85.30 [Reserved]

§ 85.31 Employment.

No qualified individuals with handicaps shall, on the basis of handicap, be subjected to discrimination in employment under any program or activity conducted by the agency. The definitions, requirements, and procedures of section 501 of the Rehabilitation Act of 1973 (9 U.S.C. 791), as established by the Equal Employment Opportunity Commission in 9 CFR Part 1613, shall apply to employment in federally conducted programs and activities.

§§ 85.32—85.40 [Reserved]

§ 85.41 Program accessibility: Discrimination prohibited.

Except as otherwise provided in § 85.42, no qualified individual with handicaps shall, because the agency's facilities are inaccessible to or unusable by such persons, be denied the benefits of, be excluded from participation in, or otherwise be subjected to discrimination under any program or activity conducted by the agency.

§ 85.42 Program accessibility: Existing facilities.

(a) *General.* The agency shall operate each program or activity so that the program or activity, when viewed in its entirety, is readily accessible to and usable by individuals with handicaps. This paragraph does not—

(1) Necessarily require the agency to make each of its existing facilities accessible to and usable by individuals with handicaps; or

(2) Require the agency to take any action that it can demonstrate would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens. In those circumstances where agency personnel believe that the proposed action would fundamentally alter the program or activity or would result in undue financial and administrative burdens, the agency has the burden of proving that compliance with § 85.42(a) would result in such alteration or burdens. The decision that compliance would result in such alteration or burdens must be made by the agency head or his or her designee after considering all agency resources available for use in the funding and operation of the conducted program or activity in question, and must be accompanied by a written statement of reasons for reaching that conclusion. If an action would result in such an alteration or such burdens, the agency shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that individuals with handicaps receive the benefits and services of the program or activity.

(b) *Methods.* (1) The agency may comply with the requirements of this section through such means as redesign of equipment, reassignment of services to accessible buildings, assignment of aides to beneficiaries, home visits, delivery of services at alternate accessible sites, alteration of existing facilities and construction of new facilities, use of accessible rolling stock, or any other methods that result in making its programs or activities readily accessible to and usable by individuals with handicaps. The agency is not required to make structural changes in existing facilities where other methods are effective in achieving compliance with this section. The agency, in making alterations to existing buildings, shall meet accessibility requirements to the extent compelled by the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151-4157), and any regulations implementing it.

(2) In choosing among available methods for meeting the requirements of this section, the agency shall give priority to those methods that offer programs and activities to qualified individuals with handicaps in the most integrated setting appropriate.

(c) *Time period for compliance.* The agency shall comply with the obligations established under this section within 60 days of the effective date of this part except where structural changes in facilities are undertaken; such changes shall be made within three years of the effective date of this part, but, in any event, as expeditiously as possible.

(d) *Transition plan.* In the event that structural changes to facilities must be undertaken to achieve program accessibility, and it is not expected that such changes can be completed within six months, the agency shall develop, within six months of the effective date of this part, a transition plan setting forth the steps necessary to complete such changes. The agency shall provide an opportunity to interested persons, including individuals with handicaps or organizations representing individuals with handicaps, to participate in the development of the transition plan by submitting comments (both oral and written). A copy of the transition plan be made available for public inspection. The plan shall, at a minimum—

(1) Identify physical obstacles in the agency's facilities that limit the accessibility of its programs or activities to individuals with handicaps;

(2) Describe in detail the methods that will be used to make the facilities accessible;

(3) Specify the schedule for taking the steps necessary to achieve compliance with this section and, if the time period of the transition plan is longer than one year, identify steps that will be taken during each year of the transition period; and

(4) Indicate the official responsible for the implementation of the plan.

§ 85.43 Program accessibility: New construction and alterations.

Each building or part of a building that is constructed or altered by, or on behalf of, or for the use of the agency shall be designed, constructed, or altered so as to be readily accessible to and usable by individuals with handicaps. The definitions, requirements, and standards of the Architectural Barriers Act (42 U.S.C. 4151-4157) as established in 41 CFR 101-19.600 to 101-19.607 apply to buildings covered by this section.

§§ 85.44—85.50 [Reserved]

§ 85.51 Communications.

(a) The agency shall take appropriate steps to ensure effective communication with applicants, participants, personnel of other Federal entities, and members of the public.

(1) The agency shall furnish appropriate auxiliary aids where necessary to afford an individual with handicaps an equal opportunity to participate in, and enjoy the benefits of, program or activity conducted by the agency.

(i) In determining what type of auxiliary aid is necessary, the agency shall give primary consideration to the requests of the individual with handicaps.

(ii) The agency need not provide individually prescribed devices, readers for personal use or study, or other devices of a personal nature.

(2) Where the agency communicates with applicants and beneficiaries by telephone, telecommunications devices for deaf persons (TDD's) or equally effective telecommunication systems shall be used to communicate with persons with impaired hearing.

(b) The agency shall ensure that interested persons, including persons with impaired vision or hearing, can obtain information as to the existence and location of accessible services, activities, and facilities.

(c) The agency shall provide signage at a primary entrance to each of its inaccessible facilities, directing users to a location at which they can obtain information about accessible facilities. The international symbol for accessibility shall be used at each primary entrance of an accessible facility.

(d) This section does not require the agency to take any action that it can demonstrate would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens. In those circumstances where agency personnel believe that the proposed action would fundamentally alter the program or activity or would result in undue financial and administrative burdens, the agency has the burden of proving that compliance with § 85.51 would result in such alteration or burdens. The decision that compliance would result in such alteration or burdens must be made by the agency head or his or her designee after considering all agency resources available for use in the funding and operation of the conducted program or activity in question and must be accompanied by a written statement of the reasons for reaching that conclusion. If an action required to comply with this section would result in such an alteration or such burdens, the agency shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that, to the maximum extent possible, individuals with handicaps receive the benefits and services of the program or activity.

§§ 85.52—85.60 [Reserved]

§ 85.61 Compliance procedures.

(a) Except as provided in paragraph (c) of this section, this section applies to all allegations of discrimination on the basis of handicap in programs or activities conducted by the agency.

(b) Responsibility for the implementation and operation of this section shall be vested in the CCR Director/Special Assistant.

(c) The agency shall process complaints alleging violations of section 504 with respect to employment according to the procedures established by the Equal Employment Opportunity Commission in 29 CFR Part 1613 pursuant to section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 791) and HHS Instruction 1613-3. Part 1613 requires complainants to obtain precomplaint counseling within 30 days of the alleged discriminatory act, and to file complaints within 15 days of the close of counseling. Responsibility for the acceptance, investigation, and the rendering of decisions with respect to employment complaints is vested in the Assistant Secretary for Personnel Administration.

(d) OCR shall accept and investigate all complete complaints for which it has jurisdiction. All complete complaints must be filed within 180 days of the alleged act of discrimination. OCR may extend this time for good cause.

(e) If OCR receives a complaint over which it does not have jurisdiction, it shall promptly notify the complainant and shall make reasonable efforts to refer the complaint to the appropriate Federal government entity.

(f) OCR shall notify the Architectural and Transportation Barriers Compliance Board upon receipt of any complaint alleging that a building or facility that is subject to the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151-4157), is not readily accessible to and usable by individuals with handicaps.

(g) Within 180 days of the receipt of a complete complaint for which it has jurisdiction, OCR shall notify the complainant of the results of the investigations in a letter containing—

(1) Findings of fact and conclusions of law;

(2) A description of a remedy for each violation found; and

(3) A notice of the right to appeal.

(h) Appeals of the findings of fact and conclusions of law or remedies must be filed by the complainant within 60 days of receipt from the agency of the letter required by § 85.61(g). OCR may extend this time for good cause.

(i) Timely appeals shall be accepted and processed by the OCR Director/Special Assistant. Decisions on such appeals shall not be heard by the person who made the initial decision.

(j) OCR shall notify the complainant of the results of the appeal within 60 days of the receipt of the request. If OCR determines that it needs additional information from the complainant, it shall have 60 days from the date it receives the additional information to make its determination on the appeal.

(k) The time limits cited in (g) and (j) above may be extended with the permission of the Assistant Attorney General.

(l) The agency may delegate its authority for conducting complaint investigations to a component agency or other Federal agencies, except that the authority for making the final determination may not be delegated.

[53 FR 25603, July 8, 1988; 53 FR 26559, July 13, 1988]

§ 85.62 Coordination and compliance responsibilities.

(a) Each component agency shall be primarily responsible for compliance with this part in connection with the programs and activities it conducts.

(b) The OCR Director/Special Assistant shall have the overall responsibility to coordinate implementation of this part. The OCR Director/Special Assistant shall have authority to conduct investigations, to conduct compliance reviews, and to initiate such other actions as may be necessary to facilitate and ensure effective implementation of and compliance with, this part.

(c) If as a result of an investigation or in connection with any other compliance or implementation activity, the OCR Director/Special Assistant determines that a component agency appears to be in noncompliance with its responsibilities under this part, OCR will undertake appropriate action with the component agency to assure compliance. In the event that OCR and the component agency are unable to agree on a resolution of any particular matter, the matter shall be submitted to the Secretary for resolution.

EDITORIAL NOTE: At the request of the Department of Health and Human Services, the "Section-by-Section Analysis" portion of the preamble of the document published at 53 FR 25595, July 8, 1988, as corrected at 53 FR 26559, July 13, 1988, follows:

SECTION-BY-SECTION ANALYSIS OF REGULATION AND RESPONSE TO COMMENTS

Where no discussion of comments follows the analysis of a section, no comments have been received thereon.

Section 85.1 Purpose.

Section 85.1 states the purpose of the rule, which is to effectuate section 119 of the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978, which amended section 504 of the Rehabilitation Act of 1973 to prohibit discrimination on the basis of handicap in programs or activities conducted by Executive agencies or the United States Postal Service.

Section 85.2 Application.

The proposed regulation covers all programs and activities conducted by the Department of Health and Human Services ("HHS" or the "agency").

This includes the following components:

- The Office of the Secretary
  - Office of the Under Secretary
  - Office of the Deputy Under Secretary
  - Office of the Assistant Secretary for Public Affairs
  - Office of the Assistant Secretary for Legislation
  - Office of the Assistant Secretary for Planning and Evaluation
  - Office of the Assistant Secretary for Management and Budget
  - Office of the Assistant Secretary for Peronnel Administration
  - Office of the General Counsel
  - Office of Inspector General
  - Office for Civil Rights
  - Office of Consumer Affairs
- Office of Human Development Services
  - Office of the Assistant Secretary for Human Development Services
  - Administration on Aging
  - Administration for Children, Youth and Families
  - Administration for Native Americans
  - Administration on Developmental Disabilities
- Public Health Service
  - Office of the Assistant Secretary for Health
  - Agency for Toxic Substances and Disease Registry
  - Alcohol, Drug Abuse and Mental Health Administration
  - Centers for Disease Control
  - Food and Drug Administration
  - Health Resources and Services Administration
  - Indian Health Service
  - National Institutes of Health
- Health Care Financing Administration
- Social Security Administration
- Family Support Administration.

Under this section, a federally conducted program or activity is, in simple terms, anything a Federal agency does. Aside from employment, there are two major categories of federally conducted programs or activities covered by this regulation: those involving general public contact as part of ongoing agency operations, and those directly administered by the agency for program beneficiaries and participants. Activities in the first category include communication with the public (telephone contacts, office walk-ins, or interviews) and the public's use of the agency's facilities. Activities in the second category include programs that provide Federal services or benefits. This regulation does not, however, apply to programs or activities conducted outside the United States that do not involve individuals with handicaps in the United States.

The *major* programs subject to this regulation are listed below. Each of the components listed above occupies facilities which the public may have occasion to visit, engages in written and oral communication with the public, and hires Federal employees. In addition, some components operate programs which involve extensive public use, as summarized below:

Office of the Secretary—No major operating programs or activities conducted directly by the Federal government.

Office of Human Development Services—No major operating programs or activities conducted directly by the Federal government.[1]

Public Health Service—Directly operated programs include the Indian Health Service, and intramural research conducted by the National Institutes of Health.[1]

Health Care Financing Administration—Directly operates the Medicare program.[1]

Social Security Administration—Directly operates the Old Age, Survivors, and Disability Insurance, and Supplemental Security Income for the Aged, Blind, and Disabled programs.

Family Support Administration—No major operating programs or activities conducted directly by the Federal government.[1]

One commenter urged the inclusion of a program operated by one component of the Office of the Secretary, and for a list of all programs and activities to be appended to the regulation. In light of the fact that all programs and activities are covered, that a comprehensive list of all programs would be very lengthy, and that such a list would have to be amended frequently as new programs are enacted and existing programs expire, the above list appears to be sufficient.

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[1] Financial assistance programs conducted through grants to States and other recipients are covered by the section 504 rule for federally assisted programs at 45 CFR Part 84.

Section 85.3 Definitions.

"Agency." For purposes of this part "agency" means the Department of Health and Human Services or any component part of the Department of Health and Human Services that conducts a program or activity covered by this part. "Component agency" means any such component part.

"Assistant Attorney General." "Asistant Attorney General" refers to the Assistant Attorney General, Civil Rights Division, United States Department of Justice.

"Auxiliary aids." "Auxiliary aids" means services or devices that enable persons with impaired sensory, manual, or speaking skills to have an equal opportunity to participate in, and enjoy the benefits of, the agency's programs or activities. The definition provides examples of commonly used auxiliary aids. Although auxiliary aids are required explicitly only by § 85.51(a)(1), they may also be necessary to meet other requirements of this regulation.

Two commenters suggested expanding the definition of "auxiliary aids" and one of them further suggested re-naming "auxiliary aids" to read "aids for reasonable accommodation" and specifically include the services of attendants.

The items set out in § 85.3 are clearly described as examples, and are not intended to constitute an exhaustive list. By giving examples rather than by including a list, other aids can be used, and, in appropriate cases, required, without amending the regulation. In certain instances, the services of attendants may indeed be appropriate; in those instances, they will fall under the definition in § 85.3. Therefore, there is no need to change the text of the regulations.

"Complete complaint." "Complete complaint" is defined to include all of the information necessary to enable the agency to investigate the complaint. The definition is necessary, because the 180 day period for the agency's investigation (*see* § 85.61(g)) begins when the agency receives a complete complaint.

Two commenters stated their belief that the definition of "complete complaint" is too restrictive, and urged language which would give the complainant specific information as to what additional information is needed, and a further 30 days to submit such information, failing which the complaint would be dismissed without prejudice, and the complainant would be so informed.

Procedures similar to this suggestion are currently in place, and complainants will be given reasonable opportunities to complete the information submitted. There appears to be no need to spell these procedures out in the regulation.

"Facility." The definition of "facility" is similar to that in the section 504 coordination regulation for federally assisted programs (28 CFR 41.3(f)), except that the term "rolling stock or other conveyances" has been added and the phrase "or interest in such property" has been deleted because the term "facility," as used in this part, refers to structures and not to intangible property rights. It should, however, be noted that this part applies to all programs and activities conducted by the agency regardless of whether the facility in which they are conducted is owned, leased, or used on some other basis by the agency. The term "facility" is used in §§ 85.41, 85.42, and 85.61(f).

One commenter proposed not to delete the phrase "or interest in such property." As previously stated, the phrase "or interest in such property" has been deleted because the term "facility," as used in this part, refers to structures and not to intangible property rights.

"Individual with Handicaps." The definition of "individual with handicaps" is identical to the definition of "handicapped person" appearing in the section 504 coordination regulation for federally assisted programs (28 CFR 41.31), and the HHS regulation for federally assisted programs (45 CFR 84.3(j)). Although section 103(d) of the Rehabilitation Act Amendments of 1986 changed the statutory term "handicapped individual" to "individual with handicaps," the legislative history of the amendment indicates that no substantive change was intended. Thus, although the term has been changed in this regulation to be consistent with the statute as amended, the definition is unchanged. In particular, although the term as revised refers to "handicaps" in the plural, it does not exclude persons who have only one handicap.

One commenter suggested that we add "sensory" to the phrase "physical or mental impairment." Since the definition set out in § 85.3 specifically includes the sense organs among the body systems whose impairment constitutes a handicap, we have not found it necessary to amend the regulation.

"OCR." "OCR" means the Office for Civil Rights of the Department of Health and Human Services.

"OCR Director/Special Assistant" means the Director of the Office for Civil Rights, who serves concurrently as the Special Assistant to the Secretary for Civil Rights, or a designee of the OCR Director/Special Assistant.

"Qualified individual with handicaps." The definition of "qualified individual with handicaps" is a revised version of the definition of "qualified handicapped person" appearing in the section 504 coordination regulation for federally assisted programs (28 CFR 41.32) and the HHS section 504 regulation for federally assisted programs (45 CFR 84.3(k)).

Paragraph (1) is an adaptation of existing definitions of "qualified handicapped person" for purposes of federally assisted preschool, elementary, and secondary education programs (*see, e.g.*, 45 CFR 84.3(k)(2)). It provides that an individual with handicaps is qualified for preschool, elementary, or secondary education programs conducted by the agency, if he or she is a member of a class of persons otherwise entitled by statute, regulation, or agency policy to receive these services from the agency. In other words, an individual with handicaps is qualified if, considering all factors other than the handicapping condition, he or she is entitled to receive educational services from the agency.

Paragraph (2) deviates from existing regulations for federally assisted programs because of intervening court decisions. It defines "qualified individual with handicaps" with regard to any program other than those covered by paragraph (1) under which a person is required to perform services or to achieve a level of accomplishment. In such programs, a qualified individual with handicaps is one who can achieve the purpose of the program without modifications in the program that the agency can demonstrate would result in a fundamental alteration in its nature. This definition reflects the decision of the Supreme Court in *Davis*.

In that case, the Court ruled that a hearing-impaired applicant to a nursing school was not a "qualified handicapped person" because her hearing impairment would prevent her from participating in the clinical training portion of the program. The Court found that, if the program were modified so as to enable the respondent to participate (by exempting her from the clinical training requirements), "she would not receive even a rough equivalent of the training a nursing program normally gives." *Id.* at 410. It also found that "the purpose of [the] program was to train persons who could serve the nursing profession in all customary ways," *Id.* at 413, and that the respondent would be unable, because of her hearing impairment, to perform some functions expected of a registered nurse. It, therefore, concluded that the school was not required by section 504 to make such modifications that would result in "a fundamental alteration in the nature of the program." *Id.* at 410.

We have incorporated the Court's language in the definition of "qualified individual with handicaps" in order to make clear that such a person must be able to participate in the program offered by the agency. The agency is required to make modifications in order to enable an applicant with handicaps to participate, but is not required to offer a program of a fundamentally different nature. The test is whether, with appropriate modifications, the applicant can achieve the purpose of the program offered, not whether the applicant could benefit or obtain results from some other program that the agency does not offer. Although the revised definition allows exclusion of some individuals with handicaps from some programs, it requires that an individual with handicaps who is capable of achieving the purpose of the program must be accommodated, provided that the modifications do not fundamentally alter the purpose of the program.

One commenter proposed inserting the second sentence from the above paragraph into the regulatory text. We believe that the use of this language in the preamble is sufficient.

Another commenter commended HHS for the discussion of *Davis*, and the cases interpreting the *Davis* decision, in order to explain why the language of this part does not precisely track that of the regulations concerning federally assisted recipients (45 CFR Part 84). Two other commenters stated their view that incorporating *Davis* and *Alexander* into the regulation was unduly restrictive, and that the differences between this part and Part 84 would result in holding HHS to a lesser standard than HHS holds recipients of Federal financial assistance.

We believe that the Supreme Court's decision in *Davis* as well as the subsequent lower court decisions following *Davis* interpret section 504 and that it is necessary to reflect those decisions in the Department's regulation. The suggested changes are therefore not being adopted.

The agency has the burden of demonstrating that a proposed modification would constitute a fundamental alteration in the nature of its program or activity. Furthermore, in demonstrating that a modification would result in such an alteration, the agency must follow the procedures established in §§ 85.42(a) and 85.51(d), which are discussed below, for demonstrating that an action would result in undue financial and administrative burdens to the agency. That is, the decision must be made by the agency head or his or her designee in writing after consideration of all resources which are legally available to the agency for the purpose, and must be accompanied by an explanation of the reasons for the decision. If the agency head determines that an action would result in a fundamental alteration, the agency must consider options that would enable the individual with handicaps to achieve the purpose of the program but would not result in such an alteration.

Two commenters suggested that the total resources of the agency be considered in determining "undue burden." Because many Department funds are earmarked for specific purposes and are therefore unavailable for use elsewhere, the entire agency budget is not an appropriate consideration.

For programs or activities which do not fall under either of the first two paragraphs, paragraph (3) adopts the existing definition of "qualified handicapped person" with respect to services (28 CFR 41.32(b)) in the coordination regulation for programs receiving Federal financial assistance. Under this definition, a qualified individual with handicaps is an individual with handicaps who meets the essential eligibility requirements for participation in the program or activity.

Paragraph (4) explains that "qualified individual with handicaps" means "qualified handicapped person" as that term is defined for purposes of employment in the EEOC regulation at 29 CFR 1613.702(f), which is made applicable to this part by § 85.31. Nothing in this part changes existing regulations pertaining to employment.

One commenter proposed using the general section 504 definition of "qualified handicapped person" in employment cases rather than the definition of the EEOC regulation. The definition has been supplied by the Equal Employment Opportunity Commission which coordinates all employment discrimination matters throughout the government. It is also the Department's view that it is important to have a uniform definition of what constitutes employment discrimination throughout the Federal government.

"Secretary" means the Secretary of the Department of Health and Human Services or the Secretary's designee.

"Section 504". This definition makes clear that, as used in this part, "section 504" applies only to programs or activities conducted by the agency itself and not to programs or activities to which it provides Federal financial assistance.

Section 85.11 Self-evaluation.

The agency shall conduct a self-evaluation of its compliance with section 504 within one year of the effective date of this regulation. The self-evaluation requirement is present in the existing section 504 coordination regulation for programs or activities receiving Federal financial assistance (28 CFR 41.5(b)(2)) and the HHS regulations for federally assisted programs (45 CFR 84.6(k)). Experience has demonstrated the self-evaluation process to be a valuable means of establishing a working relationship with individuals with handicaps that promotes both effective and efficient implementation of section 504.

One commenter stated that a three-year retention period is insufficient, and proposed that self-evaluations be kept indefinitely. The regulation requires the self-evaluation to be kept for a minimum of three years, but does not include a maximum. It is expected that the self-evaluation will be retained for the period provided in current document retention policies.

Another commenter proposed that copies of the self-evaluation be made available for copying as well as for public inspection. This proposal has been adopted.

A further commenter proposed the inclusion of provisions for assurances, transition plans and specific modification requirements. We believe that while assurances are appropriate—and can be specifically enforced—in section 504 regulations for federally assisted programs or activities, all of the entities involved in this part are under the control of the Secretary, who can issue the necessary directives; assurances are therefore not required.

The final rule provides for participation in the self-evaluation process by individuals with handicaps or organizations representing individuals with handicaps by submitting comments, which may include the development of transition plans. It is expected that component agencies will consult with individuals with handicaps among their own staff in the course of preparing self-evaluations.

Because modification requirements are intended to address any potential problems in the agency's programs or activities, they are not specified in the regulation.

Section 85.12 Notice.

Section 85.12 requires the agency to disseminate sufficient information to employees, applicants, participants, beneficiaries, and other interested persons to apprise them of the rights and protections afforded by section 504 and this part. Methods of providing this information include, for example, the publication of information in handbooks, manuals, and pamphlets that are distributed to the public to describe the agency's programs and activities or in connection with recruitment; the display of informative posters in service centers and other public places; or the broadcasting of information by television or radio.

One commenter suggested the inclusion of a reference to recruitment materials in the above examples. Such a reference has been included.

Section 85.21 General prohibitions against discrimination.

Section 85.21 is an adaptation of the corresponding section of the section 504 coordination regulation for programs and activities receiving Federal financial assistance (28 CFR 41.51).

Paragraph (a) restates the nondiscrimination mandate of section 504. The remaining paragraphs in § 85.21 establish the general principles for analyzing whether any particular action of the agency violates this mandate. These principles serve as the analytical foundation for the remaining sections of the part. If the agency violates a provision in any of the subsequent sections, it will also violate one of the general prohibitions found in § 85.21. When there is no applicable subsequent provision, the general prohibitions stated in this section apply.

Paragraph (b) prohibits overt denials of equal treatment of individuals with handicaps. The agency may not refuse to provide an individual with handicaps with an equal opportunity to participate in or benefit from its program simply because the person is handicapped. Such blatantly exclusionary practices could result from the use of irrebuttable presumptions that absolutely exclude certain classes of disabled persons (*e.g.*, epileptics, hearing-impaired persons, persons with heart ailments) from participation in programs or activities without regard to an individual's actual ability to participate. Use of an irrebuttable presumption is permissible only when in all cases a physical condition by its very nature would prevent an individual from meeting the essential eligibility requirements for participation in the activity in question. It would be permissible, therefore, to exclude without an individual evaluation all persons who are blind in both eyes from eligibility for a license to operate a commercial vehicle in interstate commerce; but it may not be permissible to automatically disqualify all those who are blind in just one eye.

In addition, section 504 prohibits more than just the most obvious denials of equal treatment. It is not enough to admit persons in wheelchairs to a program if the facilities in which the program is conducted are inaccessible. Paragraph (b)(1)(iii), therefore, requires that the opportunity to participate or benefit afforded to an individual with handicaps be as effective as that afforded to others. The later sections on program accessibility (§§ 85.41-43) and communication (§ 85.51) are specific applications of this principle.

Despite the mandate of paragraph (d) that the agency administer its programs and activities in the most integrated setting appropriate to the needs of qualified individuals with handicaps, paragraph (b)(1)(iv), in conjunction with paragraph (d), permits the agency to develop separate or different aids, benefits, or services when necessary to provide individuals with handicaps with an equal opportunity to participate in or benefit from the agency's programs or activities. Paragraph (b)(1)(iv) requires that different or separate aids, benefits, or services be provided only when necessary to ensure that the aids, benefits, or services are as effective as those provided to others. Even when separate or different aids, benefits or services would be more effective, paragraph (b)(2) provides that a qualified individual with handicaps still has the right to choose to participate in the program that is not designed to accommodate individuals with handicaps.

Paragraph (b)(1)(v) prohibits the agency from denying a qualified individual with handicaps the opportunity to participate as a member of a planning or advisory board.

Paragraph (b)(1)(vi) prohibits the agency from limiting a qualified individual with handicaps in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving any aid, benefit, or service.

Paragraph (b)(3) prohibits the agency from utilizing criteria or methods of administration that deny individuals with handicaps access to the agency's programs or activities. The phrase "criteria or methods of administration" refers to official written agency policies, as well as the actual practices of the agency. This paragraph prohibits both blatantly exclusionary policies or practices and nonessential policies and practices that are neutral on their face, but deny individuals with handicaps an effective opportunity to participate.

Paragraph (b)(4) specifically applies the prohibition enuciated in § 85.21(b)(3) to the process of selecting sites for construction of new facilities or existing facilities to be used by the agency. Paragraph (b)(4) does not apply to construction of additional buildings at an existing site.

Paragraph (b)(5) prohibits the agency, in the selection of procurement contractors, from using criteria that subject qualified individuals with handicaps to discrimination on the basis of handicap.

Paragraph (b)(6) prohibits the agency from discriminating against qualified individuals with handicaps on the basis of handicap in the granting of licenses or certifications. A person is a "qualified individual with handicaps" with respect to licensing or certification if he or she can meet the essential eligibility requirements for receiving the license or certification (*see* § 85.3).

In addition, the agency may not establish requirements for the programs or activities of licensees or certified entities that subject qualified individuals with handicaps to discrimination on the basis of handicap. For example, the agency must comply with this requirement when establishing safety standards for the operations of licensees. In that case, the agency must ensure that the standards it promulgates do not discriminate against the employment of qualified individuals with handicaps in an impermissible manner.

Paragraph (b)(6) does not extend section 504 directly to the programs or activities of licensees or certified entities themselves. The programs or activities of Federal licensees or certified entities are not themselves federally conducted programs or activities; nor are they programs or activities receiving Federal financial assistance merely by virtue of the Federal license or certificate. However, as noted above, section 504 may affect the content of the rules established by the agency for the operation of the program or activity of the licensee or certified entity and thereby indirectly affect limited aspects of their operations.

One commenter suggested pointing out that Federal licensees or certified entities, having received services from Federal employees during the process of licensing or certification, thereby become Federally assisted recipients, and are covered by 45 CFR Part 84. Such an argument is beyond the scope of this part; and is therefore not being included.

Another commenter suggested including language such as that found in 45 CFR 84.4(b)(1) to the effect that agencies may not perpetuate discrimination against qualified individuals with handicaps by providing significant assistance to an agency, organization or person that discriminates on the basis of handicap. Assistance from the agency that would provide significant support to an organization constitutes Federal financial assistance and the organization, as a recipient of such assistance, would be covered by the section 504 regulation for federally assisted programs.

Paragraph (c) provides that programs conducted pursuant to Federal statute or Executive order that are designed to benefit only individuals with handicaps or a given class of individuals with handicaps may be limited to individuals those with handicaps.

Paragraph (d) provides that the agency must administer programs and activities in the most integrated setting appropriate to the next of qualified individuals with handicaps, *i.e.* in a setting that enables individuals with handicaps to interact with nonhandicapped individuals to the fullest extent possible.

Section 85.31 Employment.

Section 85.31 prohibits discrimination on the basis of handicap in employment by the agency. Courts have held that section 504, as amended in 1978, covers the employment practices of Executive agencies. *Gardner* v. *Morris*, 752 F.2d 1271, 1277 (8th Cir. 1985); *Smith* v. *United States Postal Service*, 742 F.2d 257, 259–60 (6th Cir. 1984); *Prewitt* v. *United States Postal Service*, 662 F.2d 292, 302–04 (5th Cir. 1981). *Contra McGuiness* v. *United States Postal Service*, 744 F.2d 1318, 1320–21 (7th Cir. 1984); *Boyd* v. *United States Postal Service*, 752 F.2d 410, 413–14 (9th Cir. 1985).

Courts uniformly have held that, in order to give effect to section 501 of the Rehabilitation Act, which covers Federal employment, the administrative procedures of section 501 must be followed in processing complaints of employment discrimination under section 504. *Morgan* v. *United States Postal Service*, 798 F.2d 1162, 1164–65 (8th Cir. 1986); *Smith*, 742 F.2d at 262; *Prewitt*, 662 F.2d at 304. Accordingly, § 85.31 (Employment) of this rule adopts the definitions, requirements, and procedures of section 501 as established in regulations of the EEOC at 29 CFR Part 1613. Responsibility for coordinating enforcement of Federal laws prohibiting discrimination in employment is assigned to the EEOC by Executive Order 12067 (3 CFR, 1978 Comp., p. 206). Under this authority, the EEOC establishes government-wide standards on nondiscrimination in employment on the basis of handicap.

One commenter proposed that the general definition of "qualified individual with handicaps" be used in this section, instead of that used under section 501. We believe that the above paragraphs sufficiently explain the need for using the section 501 definition.

In addition to this section, § 85.61(c) specifies that the agency will use the existing EEOC procedures to resolve allegations of employment discrimination.

Section 85.41 Program accessibility: Discrimination prohibited.

Section 85.41 states the general nondiscrimination principle underlying the program accessibility requirements of §§ 85.42 and 85.43.

Section 85.42 Program accessibility: Existing facilities.

This part adopts the program accessibility concept found in the existing section 504 coordination regulation for programs or activities receiving Federal financial assistance (28 CFR 41.57) with certain modifications. Thus, § 85.42 requires that each agency program or activity, when viewed in its entirety, be readily accessible to and usable by individuals with handicaps. The part also makes clear that the agency is not required to make each of its existing facilities accessible (§ 85.42(a)(1)). However, § 85.42, unlike 28 CFR 41.57, places explicit limits on the agency's obligation to ensure program accessibility (§ 85.42(a)(2)).

One commenter stated that the provisions of § 85.42(a)(1) were negatively worded and may reflect a misinterpretation of the decision of the Supreme Court in *Grove City*

College v. *Bell*, 465 U.S. 555 (1984), and argued for deletion of this language.

The language is identical to that in the section 504 regulation for federally assisted programs or activities. We believe that the inclusion of this language is necessary in order to make clear that, while every aspect of every Federal program or activity need not be accessible, each program or activity, when viewed as a whole, must be accessible.

Another commenter recommended adding the language "where other methods are equally effective in achieving compliance" from § 84.42(b) to § 84.42(a)(1). We believe that, because §§ 84.42 (a) and (b) treat different aspects of the subject, their language must necessarily differ.

Paragraph (a)(2) generally codifies recent case law that defines the scope of the agency's obligation to ensure program accessibility. This paragraph provides that in meeting the program accessibility requirement, the agency is not required to take any action that would result in a fundamental alteration in the nature of its program or activity, or in undue financial and administrative burdens. A similar limitation is provided in § 85.51(d). This provision is based on the Supreme Court's holding in *Southeastern Community College* v. *Davis*, 442 U.S. 397 (1979), that section 504 does not require program modifications that result in a fundamental alteration in the nature of a program, and on the Court's statement that section 504 does not require modifications that would result in "undue financial and administrative burdens." 442 U.S. at 412. Since *Davis*, circuit courts have applied this limitation on a showing that only one of the two "undue burdens" would be created as a result of the modification sought to be imposed under section 504. *See, e.g., Dopico* v. *Goldschmidt*, 687 F.2d 644 (2d Cir. 1982); *American Public Transit Association* v. *Lewis*, 655 F.2d 1272 (D.C. Cir. 1981).

Paragraph (a)(2) and § 85.51(d) are also supported by the Supreme Court's decision in *Alexander* v. *Choate*, 469 U.S. 287 (1985). *Alexander* involved a challenge to the State of Tennessee's reduction of inpatient hospital care coverage under Medicaid from 20 to 14 days per year. Plaintiffs argued that this reduction violated section 504 because it had an adverse impact on handicapped persons. The Court assumed without deciding that section 504 reaches at least some conduct that has an unjustifiable disparate impact on handicapped people, but held that the reduction was not "the sort of disparate impact" discrimination that might be prohibited by section 504 or its implementing regulation. *Id* at 299.

Relying on *Davis*, the Court said that section 504 guarantees qualified handicapped persons "meaningful access to the benefits the grantee offers," *id.* at 301, and that "*reasonable adjustments* in the nature of the benefit offered must at times be made to assure meaningful access." *Id.* n.21 (emphasis added). However, section 504 does not require "'changes,' 'adjustments,' or 'modifications' to existing programs that would be 'substantial' * * * or that would constitute 'fundamental alteration[s] in the nature of a program.'" *Id.* at n.20 (citations omitted). *Alexander* supports the position, based on *Davis* and the earlier lower court decisions, that in some situations, certain accommodations for a handicapped person may so alter an agency's program or activity, or entail such extensive costs and administrative burdens that the refusal to undertake the accommodations is not discriminatory. Thus, failure to include such an "undue burdens" provision could lead to judicial invalidation of the regulation or reversal of a particular enforcement action taken pursuant to the regulation.

This paragraph, however, does not establish an absolute defense; it does not relieve the agency of all obligations to individuals with handicaps. Although the agency is not required to take actions that would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens, it nevertheless must take any other steps necessary to ensure that individuals with handicaps receive the benefits and services of the federally conducted program or activity.

It is our view that compliance with § 85.42(a) would in most cases not result in undue financial and administrative burdens on the agency. In determining whether financial and administrative burdens are undue, all agency resources available for use in the funding and operation of the conducted program or activity should be considered. The burden of proving that compliance with § 85.42(a) would fundamentally alter the nature of a program or activity or would result in undue financial and administrative burdens rests with the agency. The decision that compliance would result in such alteration or burdens must be made by the agency head or his or her designee, and must be accompanied by a written statement of the reasons for reaching that conclusion. Any person who believes that he or she or any specific class of persons has been injured by the agency head's decision or failure to make a decision may file a complaint under the compliance procedures established in § 85.61. The opportunity to file such a complaint responds to one commenter's suggestion that review by a high level Department official be assured.

Paragraph (b)(1) sets forth a number of means by which program accessibility may be achieved, including redesign of equipment, reassignment of services to accessible buildings, and provision of aides. In choosing among methods, the agency shall give priority consideration to those that will be consistent with provision of services in the most integrated setting appropriate to the needs of individuals with handicaps. Structural changes in existing facilities are required only when there is no other feasible way to make the agency's program accessible. (It should be noted that "structural changes" include all physical changes to a facility; the term does not refer only to changes to structural features, such as removal of or alteration to a load-bearing structural member.) The agency may comply with the program accessibility requirement by delivering services at alternate accessible sites or making home visits as appropriate.

One commenter proposed that methods other than structural changes to ensure accessibility should be "equally effective". The regulations implementing section 504 for federally assisted programs do not contain such language. The addition of the proposed language would impose a regulatory standard on the Department not required of recipients. In view of the fact that the 1978 amendments were intended to apply the same requirements to federally conducted programs as apply to federally assisted programs, the proposed language is not being adopted.

Paragraphs (c) and (d) establish time periods for complying with the program accessibility requirement. As currently required for federally assisted programs by 28 CFR 41.57(b), the agency must make any necessary structural changes in facilities as soon as practicable, but in no event later than three (3) years after the effective date of this part. Where structural modifications are required and it is not expected that these can be completed within six months, a transition plan should be developed within six months of the effective date of this part. Aside from structural changes, all other necessary steps to achieve compliance shall be taken within sixty days.

One commenter proposes to limit the time allowed for making structural modifications to one year. We note that the basic requirement is that these changes be made "as soon as practicable," and that the three-year limit is the maximum period of time. Furthermore, the three-year maximum for transition plans is identical to that contained in the regulations for federally assisted recipients.

Section 85.43 Program accessibility: New construction and alterations.

Overlapping coverage exists with respect to new construction and alterations under section 504 and the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151-4157). Section 85.43 provides that those buildings that are constructed or altered by, on behalf of, or for the use of the agency shall be designed, constructed, or altered to be readily accessible to and usable by individuals with handicaps in accordance with 41 CFR Part 101-19, 101-19.600 to 101-19.607 (GSA regulation which incorporates the Uniform Federal Accessibility Standards). This standard was promulgated pursuant to the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151-4157). We believe that it is appropriate to adopt the existing Architectural Barriers Act standard for section 504 compliance because new and altered buildings subject to this regulation are also subject to the Architectural Barriers Act and because adoption of the standard will avoid duplicative and possibly inconsistent standards.

Existing buildings leased by the agency after the effective date of this regulation are not required by the regulation to meet accessibility standards simply by virtue of being leased. They are subject, however, to the program accessibility standards for existing facilities in § 85.42. To the extent the buildings are newly constructed or altered, they must also meet the new constructions and alteration requirements of § 85.43.

Federal practice under section 504 has always treated newly leased buildings as subject to the existing facility program accessibility standard. Unlike the construction of new buildings where architectural barriers can be avoided at little or no cost, the application of new construction standards to an existing building being leased raises the same prospect of retrofitting buildings as the use of an existing Federal facility, and the agency believes that same program accessibility standards should apply to both owned and leased existing buildings.

In *Rose* v. *United States Postal Service*, 774 F.2d 1355 (9th Cir. 1985), the Ninth Circuit held that the Architectural Barriers Act requires accessibility at the time of lease. The *Rose* court did not address the question of whether section 504 likewise requires accessibility as a condition of lease, and the case was remanded to the District Court for, among other things, consideration of this issue. Two commenters urged that leased buildings be required to be accessible at the time of lease. The agency may provide more specific guidance on section 504 requirements for leased buildings after the litigation is completed.

Section 85.51 Communications.

Section 85.51 requires the agency to take appropriate steps to ensure effective communication with personnel of other Federal entities, applicants, participants, and members of the public. These steps shall include procedures for determining when auxiliary aids are necessary under § 85.1(a)(1) to afford an individual with handicaps an equal opportunity to participate in, and enjoy the benefits of, the agency's program or activity. They shall also include an opportunity for individuals with handicaps to request the auxiliary aids of their choice. This expressed choice shall be given primary consideration by the agency (§ 85.51(a)(1)(i)). The agency shall honor the choice unless it can demonstrate that another effective means of communication exists or that use of the means chosen would not be required under § 85.51(d). That paragraph limits the obligations of the agency to ensure effective communication in accordance with *Davis* and the circuit court opinions interpreting it (*see supra* preamble discussion of § 85.42(c)(2)). Unless not required by § 85.51(d), the agency shall provide auxiliary aids at no cost to the individual with handicaps.

One commenter proposed that the choice of auxiliary aid made by the individual with handicaps should govern unless it would constitute an undue hardship on the agency. We believe that the language set out above is adequate to ensure consideration of an individual's preference.

Another commenter proposed that the regulation require all films and videotapes produced by the agency to be captioned for the hearing-impaired. The Department intends to examine all appropriate methods of ensuring effective communication.

The same commenter applauded HHS for the inclusion of the language requiring HHS to inform individuals with handicaps of their section 504 rights.

The discussion of § 85.42(a), Program accessibility, Existing facilities, regarding the determination of what constitutes undue financial and administrative burdens, also applies to § 85.51(d) and should be referred to for a complete understanding of the agency's obligation to comply with § 85.51.

In some circumstances, a notepad and written materials may be sufficient to permit effective communication with a hearing-impaired person. In many circumstances, however, they may not be, particularly when the information being communicated is complex or exchanged for a lengthy period of time (*e.g.* a meeting) or where the hearing-impaired applicant or participant is not skilled in spoken or written language. In these cases, a sign language interpreter may be appropriate.

One commenter proposed changing the language to state that notepads rarely suffice for communication with the hearing-impaired. Considering that a significant number of the hearing-impaired may not be skilled in sign language, we believe that the language used is appropriate.

For vision-impaired persons, effective communication might be achieved by several means, including readers and audio recordings. In general, the agency intends to inform the public of (1) the communications services it offers to afford individuals with handicaps an equal opportunity to participate in or benefit from its programs and activities, (2) the opportunity to request a particular mode of communication, and (3) the agency's preferences regarding auxiliary aids if it can demonstrate that several different modes are effective.

The agency shall ensure effective communication with vision-impaired and hearing-impaired persons involved in proceedings conducted by the agency. Auxiliary aids must be afforded where necessary to ensure effective communication at the proceedings. If sign language interpreters are necessary, the agency may require that it be given reasonable notice prior to the proceedings of the need for an interpreter. Moreover, the agency need not provide individually prescribed devices, readers for personal use or study, or other devices of a personal nature (§ 85.51(a)(1)(ii)). For example, the agency need not provide eye glasses or hearing aids to applicants or participants in its programs. Similarly, the regulation does not require the agency to provide wheelchairs to persons with mobility impairments.

One commenter proposed that the items which agencies are not required to provide and the circumstances involved be described in more detail. We believe that the description given is sufficient, because the interpretation of this provision will be made on a case-by-case basis.

Paragraph (b) requires the agency to ensure that individuals with handicaps can obtain information concerning accessible services, activities, and facilities.

Paragraph (c) requires the agency to provide signage at inaccessible facilities that direct users to locations with information about accessible facilities.

One commenter suggested specifically mentioning the international symbol for deafness, and placing such signs at the main entrance of buildings equipped to service the hearing-impaired. We believe that the language contained in §§ 85.51 (b) and (c) requires the agency to ensure that individuals with handicaps, including those with impaired hearing, can obtain information regarding accessibility, and that this requirement is sufficient to afford flexibility on the part of the agency regarding use of appropriate signage.

One commenter proposed adding the words "in the most integrated setting appropriate" to the language in § 85.51(d). This language already appears elsewhere in the regulation, *e.g.* in § 85.42(b)(2), and it is the Department's intention to act in accordance with that provision.

Section 85.61 Compliance procedures.

Paragraph (a) specifies that paragraphs (b) and (d) through (l) of this section establish the procedures for processing complaints other than employment complaints. Paragraph (c) provides that the agency will process employment complaints according to procedures established in existing regulations of the EEOC (29 CFR Part 1613) pursuant to section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 791).

Paragraph (b) designates the official responsible for coordinating implementation of § 85.61. The NPRM stated that responsibility for the implementation and operation of this "part" shall be vested in the OCR Director/Special Assistant. The final rule has been revised by replacing the word "part" with the word "section" to clarify the responsibility for coordinating implementation of § 85.61.

The agency is required to accept and investigate all complete complaints (§ 85.61(d)). Two commenters suggested that a complainant have an opportunity to remedy an incomplete complaint. Current administrative procedures provide for this practice and it need not be included in the text of the regulation.

If the agency determines that it does not have jurisdiction over a complaint, it shall promptly notify the complainant and make reasonable efforts to refer the complaint to the appropriate entity of the Federal Government (§ 85.61(e)). One commenter pointed out that where a reference to another entity of the Federal government is required, the obligation to refer should be absolute, not limited to reasonable efforts. The language "shall make reasonable efforts to refer" is not intended to minimize the Department's obligation.

Paragraph (f) requires the agency to notify the Architectural and Transportation Barriers Compliance Board (ATBCB) upon receipt of a complaint alleging that a building or facility subject to the Architectural Barriers Act was designed, constructed, or altered in a manner that does not provide ready access and use by individuals with handicaps.

Paragraph (g) requires the agency to provide to the complainant, in writing, findings of fact and conclusions of law, the relief granted if noncompliance is found, and notice of the right to appeal (§ 85.61(g)). One appeal within the agency shall be provided (§ 85.61(i)). The appeal will not be heard by the same person who made the initial determination of compliance or noncompliance.

Paragraph (l) permits the agency to delegate its authority for investigating complaints to other Federal agencies. However, the statutory obligation of the agency to make a final determination of compliance or noncompliance may not be delegated.

Commenters have suggested the following:

Notifying complainants whenever their complaints are referred to another agency. Current administrative procedures provide for this practice and it need not be included in the text of the regulation.

Describing the basic parameters for submitting or obtaining evidence used to decide appeals. Since the grounds for appeal may be extremely varied, it would not be practicable to set out parameters for every appeal.

Including a statement as to complainants' rights to judicial review. These rights are statutory and beyond the scope of this regulation.

Obtaining the expertise of ATBCB in appropriate cases. A provision regarding notification of ATBCB is already included in the regulation.

Including a statement that all other regulations, forms and directives issued by HHS are superseded by the nondiscrimination requirements of this part. The Department views any other issuances falling short of the requirements of this regulation as insufficient to ensure compliance and therefore such a statement is unnecessary.

Provisions for attorneys fees and compensation to the prevailing party. Such provisions are statutory and beyond the scope of this regulation.

Section 85.62 Coordination and compliance responsibilities.

Section 85.62 sets out the respective responsibilities of the components of HHS and of the Director, OCR/Special Assistant in the implementation of section 504 to programs and activities conducted by HHS.

Paragraph (c) specifies the respective roles of OCR and of the HHS component in cases in which noncompliance is found.

In the event that OCR and the HHS component cannot agree on a resolution of any particular matter, such matter will be submitted to the Secretary for resolution.

PART 86—NONDISCRIMINATION ON THE BASIS OF SEX IN EDUCATION PROGRAMS AND ACTIVITIES RECEIVING OR BENEFITING FROM FEDERAL FINANCIAL ASSISTANCE

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SUBJECT INDEX TO TITLE IX PREAMBLE AND REGULATION

APPENDIX A TO PART 86—GUIDELINES FOR ELIMINATING DISCRIMINATION AND DENIAL OF SERVICES ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, SEX, AND HANDICAP IN VOCATIONAL EDUCATION PROGRAMS [NOTE]

SOURCE: 40 FR 24137, June 4, 1975, unless otherwise noted.

Subpart A—Introduction

§ 86.1 Purpose and effective date.

The purpose of this part is to effectuate title IX of the Education Amendments of 1972, as amended by Pub. L. 93-568, 88 Stat. 1855 (except sections 904 and 906 of those Amendments) which is designed to eliminate (with certain exceptions) discrimination on the basis of sex in any education program or activity receiving Federal financial assistance, whether or not such program or activity is offered or sponsored by an educational institution as defined in this part. This part is also intended to effectuate section 844 of the Education Amendments of 1974, Pub. L. 93-380, 88 Stat. 484. The effective date of this part shall be July 21, 1975.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682, as amended by Pub. L. 93-568, 88 Stat. 1855, and sec. 844, Education Amendments of 1974, 88 Stat. 484, Pub. L. 93-380)

§ 86.2 Definitions.

As used in this part, the term—

(a) *"Title IX"* means title IX of the Education Amendments of 1972, Pub. L. 92-318, as amended by section 3 of Pub. L. 93-568, 88 Stat. 1855, except sections 904 and 906 thereof; 20 U.S.C. 1681, 1682, 1683, 1685, 1686.

(b) *"Department"* means the Department of Health and Human Services.

(c) *"Secretary"* means the Secretary of Health and Human Services.

(d) *"Director"* means the Director of the Office for Civil Rights of the Department.

(e) *"Reviewing Authority"* means that component of the Department delegated authority by the Secretary to appoint, and to review the decisions of, administrative law judges in cases arising under this part.

(f) *"Administrative law judge"* means a person appointed by the reviewing authority to preside over a hearing held under this part.

(g) *"Federal financial assistance"* means any of the following, when authorized or extended under a law administered by the Department:

(1) A grant or loan of Federal financial assistance, including funds made available for:

(i) The acquisition, construction, renovation, restoration, or repair of a building or facility or any portion thereof; and

(ii) Scholarships, loans, grants, wages or other funds extended to any entity for payment to or on behalf of students admitted to that entity, or extended directly to such students for payment to that entity.

(2) A grant of Federal real or personal property or any interest therein, including surplus property, and the proceeds of the sale or transfer of such property, if the Federal share of the fair market value of the property is not, upon such sale or transfer, properly accounted for to the Federal Government.

(3) Provision of the services of Federal personnel.

(4) Sale or lease of Federal property or any interest therein at nominal consideration, or at consideration reduced for the purpose of assisting the recipient or in recognition of public interest to be served thereby, or permission to use Federal property or any interest therein without consideration.

(5) Any other contract, agreement, or arrangement which has as one of its purposes the provision of assistance to any education program or activity, except a contract of insurance or guaranty.

(h) *"Recipient"* means any State or political subdivision thereof, or any instrumentality of a State or political subdivision thereof, any public or private agency, institution, or organization, or other entity, or any person, to whom Federal financial assistance is extended directly or through another recipient and which operates an education program or activity which receives or benefits from such assistance, including any subunit, successor, assignee, or transferee thereof.

(i) *"Applicant"* means one who submits an application, request, or plan required to be approved by a Department official, or by a recipient, as a condition to becoming a recipient.

(j) *"Educational institution"* means a local educational agency (L.E.A.) as defined by section 801(f) of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 881), a preschool, a private elementary or secondary school, or an applicant or recipient of the type defined by paragraph (k), (l), (m), or (n) of this section.

(k) *"Institution of graduate higher education"* means an institution which:

(1) Offers academic study beyond the bachelor of arts or bachelor of science degree, whether or not leading to a certificate of any higher degree in the liberal arts and sciences; or

(2) Awards any degree in a professional field beyond the first professional degree (regardless of whether the first professional degree in such field is awarded by an institution of undergraduate higher education or professional education); or

(3) Awards no degree and offers no further academic study, but operates ordinarily for the purpose of facilitating research by persons who have received the highest graduate degree in any field of study.

(l) *"Institution of undergraduate higher education"* means:

(1) An institution offering at least two but less than four years of college level study beyond the high school level, leading to a diploma or an associate degree, or wholly or principally creditable toward a baccalaureate degree; or

(2) An institution offering academic study leading to a baccalaureate degree; or

(3) An agency or body which certifies credentials or offers degrees, but which may or may not offer academic study.

(m) *"Institution of professional education"* means an institution (except any institution of undergraduate higher education) which offers a program of academic study that leads to a first professional degree in a field for which there is a national specialized accrediting agency recognized by the United States Commissioner of Education.

(n) *"Institution of vocational education"* means a school or institution (except an institution of professional or graduate or undergraduate higher education) which has as its primary purpose preparation of students to pursue a technical, skilled, or semiskilled occupation or trade, or to pursue study in a technical field, whether or not the school or institution offers certificates, diplomas, or degrees and whether or not it offers fulltime study.

(o) *"Administratively separate unit"* means a school, department or college of an educational institution (other than a local educational agency) admission to which is independent of admission to any other component of such institution.

(p) *"Admission"* means selection for part-time, full-time, special, associate, transfer, exchange, or any other enrollment, membership, or matriculation in or at an education program or activity operated by a recipient.

(q) *"Student"* means a person who has gained admission.

(r) *"Transition plan"* means a plan subject to the approval of the United States Commissioner of Education pursuant to section 901(a)(2) of the Education Amendments of 1972, under which an educational institution operates in making the transition from being an educational institution which admits only students of one sex to being one which admits students of both sexes without discrimination.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.3 Remedial and affirmative action and self-evaluation.

(a) *Remedial action.* If the Director finds that a recipient has discriminated against persons on the basis of sex in an education program or activity, such recipient shall take such remedial action as the Director deems necessary to overcome the effects of such discrimination.

(b) *Affirmative action.* In the absence of a finding of discrimination on the basis of sex in an education program or activity, a recipient may take affirmative action to overcome the effects of conditions which resulted in limited participation therein by persons of a particular sex. Nothing herein shall be interpreted to alter any affirmative action obligations which a recipient may have under Executive Order 11246.

(c) *Self-evaluation.* Each recipient education institution shall, within one year of the effective date of this part:

(1) Evaluate, in terms of the requirements of this part, its current policies and practices and the effects thereof concerning admission of students, treatment of students, and employment of both academic and non-academic personnel working in connection with the recipient's education program or activity;

(2) Modify any of these policies and practices which do not or may not meet the requirements of this part; and

(3) Take appropriate remedial steps to eliminate the effects of any discrimination which resulted or may have resulted from adherence to these policies and practices.

(d) *Availability of self-evaluation and related materials.* Recipients shall maintain on file for at least three years following completion of the evaluation required under paragraph (c) of this section, and shall provide to the Director upon request, a description of any modifications made pursuant to paragraph (c) (2) of this section and of any remedial steps taken pursuant to paragraph (c) (3) of this section.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

[40 FR 24128, June 4, 1975; 40 FR 39506, Aug. 28, 1975]

§ 86.4 Assurance required.

(a) *General.* Every application for Federal financial assistance for any education program or activity shall as condition of its approval contain or be accompanied by an assurance from the applicant or recipient, satisfactory to the Director, that each education program or activity operated by the applicant or recipient and to which this part applies will be operated in compliance with this part. An assurance of compliance with this part shall not be satisfactory to the Director if the applicant or recipient to whom such assurance applies fails to commit itself to take whatever remedial action is necessary in accordance with § 86.3(a) to eliminate existing discrimination on the basis of sex or to eliminate the effects of past discrimination whether occurring prior or subsequent to the submission to the Director of such assurance.

(b) *Duration of obligation.* (1) In the case of Federal financial assistance extended to provide real property or structures thereon, such assurance shall obligate the recipient or, in the case of a subsequent transfer, the transferee, for the period during which the real property or structures are used to provide an education program or activity.

(2) In the case of Federal financial assistance extended to provide personal property, such assurance shall obligate the recipient for the period during which it retains ownership or possession of the property.

(3) In all other cases such assurance shall obligate the recipient for the period during which Federal financial assistance is extended.

(c) *Form.* The Director will specify the form of the assurances required by paragraph (a) of this section and the extent to which such assurances will be required of the applicant's or recipient's subgrantees, contractors, subcontractors, transferees, or successors in interest.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.5 Transfers of property.

If a recipient sells or otherwise transfers property financed in whole or in part with Federal financial assistance to a transferee which operates any education program or activity, and the Federal share of the fair market value of the property is not upon such sale or transfer properly accounted for to the Federal Government both the transferor and the transferee shall be deemed to be recipients, subject to the provisions of Subpart B of this part.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.6 Effect of other requirements.

(a) *Effect of other Federal provisions.* The obligations imposed by this part are independent of, and do not alter, obligations not to discriminate on the basis of sex imposed by Executive Order 11246, as amended; sections 799A and 845 of the Public Health Service Act (42 U.S.C. 295h-9 and 298b-2); Title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e et seq.); the Equal Pay Act (29 U.S.C. 206 and 206(d)); and any other Act of Congress or Federal regulation.

(Secs. 901, 902, 905, Education Amendments of 1972, 86 Stat. 373, 374, 375; 20 U.S.C. 1681, 1682, 1685)

(b) *Effect of State or local law or other requirements.* The obligation to comply with this part is not obviated or alleviated by any State or local law or other requirement which would render any applicant or student ineligible, or limit the eligibility of any applicant or student, on the basis of sex, to practice any occupation or profession.

(c) *Effect of rules or regulations of private organizations.* The obligation to comply with this part is not obviated or alleviated by any rule or regulation of any organization, club, athletic or other league, or association which would render any applicant or student ineligible to participate or limit the eligibility or participation of any applicant or student, on the basis of sex, in any education program or activity operated by a recipient and which receives or benefits from Federal financial assistance.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.7 Effect of employment opportunities.

The obligation to comply with this part is not obviated or alleviated because employment opportunities in any occupation or profession are or may be more limited for members of one sex than for members of the other sex.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.8 Designation of responsible employee and adoption of grievance procedures.

(a) *Designation of responsible employee.* Each recipient shall designate at least one employee to coordinate its efforts to comply with and carry out its responsibilities under this part, including any investigation of any complaint communicated to such recipient alleging its noncompliance with this part or alleging any actions which would be prohibited by this part. The recipient shall notify all its students and employees of the name, office address and telephone number of the employee or employees appointed pursuant to this paragraph.

(b) *Complaint procedure of recipient.* A recipient shall adopt and publish grievance procedures providing for prompty and equitable resolution of student and employee complaints alleging any action which would be prohibited by this part.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.9 Dissemination of policy.

(a) *Notification of policy.* (1) Each recipient shall implement specific and continuing steps to notify applicants for admission and employment, students and parents of elementary and secondary school students, employees, sources of referral of applicants for admission and employment, and all unions or professional organizations holding collective bargaining or professional agreements with the recipient, that it does not discriminate on the basis of sex in the educational programs or activities which it operates, and that is required by title IX and this part not to discriminate in such a manner. Such notification shall contain such information, and be made in such manner, as the Director finds necessary to apprise such persons of the protections against discrimination assured them by title IX and this part, but shall state at least that the requirement not to discriminate in education programs and activities extends to employment therein, and to admission thereto unless Subpart C does not apply to the recipient, and that inquiries concerning the application of title IX and this part to such recipient may be referred to the employee designated pursuant to § 86.8, or to the Director.

(2) Each recipient shall make the initial notification required by paragraph (a) (1) of this section within 90 days of the effective date of this part or of the date this part first applies to such recipient, whichever comes later, which notification shall include publication in:

(i) Local newspapers;

(ii) Newspapers and magazines operated by such recipient or by student, alumnae, or alumni groups for or in connection with such recipient; and

(iii) Memoranda or other written communications distributed to every student and employee of such recipient.

(b) *Publications.* (1) Each recipient shall prominently include a statement of the policy described in paragraph (a) of this section in each announcement, bulletin, catalog, or application form which it makes available to any person of a type, described in paragraph (a) of this section, or which is otherwise used in connection with the recruitment of students or employees.

(2) A recipient shall not use or distribute a publication of the type described in this paragraph which suggests, by text or illustration, that such recipient treats applicants, students, or employees differently on the basis of sex except as such treatment is permitted by this part.

(c) *Distribution.* Each recipient shall distribute without discrimination on the basis of sex each publication described in paragraph (b) of this section, and shall apprise each of its admission and employment recruitment representatives of the policy of nondiscrimination described in paragraph (a) of this section, and require such representatives to adhere to such policy.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

Subpart B—Coverage

§ 86.11 Application.

Except as provided in this subpart, this Part 86 applies to every recipient and to each education program or activity operated by such recipient which receives or benefits from Federal financial assistance.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.12 Educational institutions controlled by religious organizations.

(a) *Application.* This part does not apply to an educational institution which is controlled by a religious organization to the extent application of this part would not be consistent with the religious tenets of such organization.

(b) *Exemption.* An educational institution which wishes to claim the exemption set forth in paragraph (a) of this section, shall do so by submitting in writing to the Director a statement by the highest ranking official of the institution, identifying the provisions of this part which conflict with a specific tenet of the religious organization.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.13 Military and merchant marine educational institutions.

This part does not apply to an educational institution whose primary purpose is the training of individuals for a military service of the United States or for the merchant marine.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.14 Membership practices of certain organizations.

(a) *Social fraternities and sororities.* This part does not apply to the membership practices of social fraternities and sororities which are exempt from taxation under section 501(a) of the Internal Revenue Code of 1954, the active membership of which consists primarily of students in attendance at institutions of higher education.

(b) *YMCA, YWCA, Girl Scouts, Boy Scouts and Camp Fire Girls.* This part does not apply to the membership practices of the Young Men's Christian Association, the Young Women's Christian Association, the Girl Scouts, the Boy Scouts and Camp Fire Girls.

(c) *Voluntary youth service organizations.* This part does not apply to the membership practices of voluntary youth service organizations which are exempt from taxation under section 501(a) of the Internal Revenue Code of 1954 and the membership of which has been traditionally limited to members of one sex and principally to persons of less than nineteen years of age.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682; sec. 3(a) of Pub. L. 93-568, 88 Stat. 1862 amending sec. 901)

§ 86.15 Admissions.

(a) Admissions to educational institutions prior to June 24, 1973, are not covered by this part.

(b) *Administratively separate units.* For the purposes only of this section, §§ 86.16 and 86.17, and Subpart C, each administratively separate unit shall be deemed to be an educational institution.

(c) *Application of Subpart C.* Except as provided in paragraphs (d) and (e) of this section, Subpart C applies to each recipient. A recipient to which Subpart C applies shall not discriminate on the basis of sex in admission or recruitment in violation of that subpart.

(d) *Educational institutions.* Except as provided in paragraph (e) of this section as to recipients which are educational institutions, Subpart C applies only to institutions of vocational education, professional education, graduate higher education, and public institutions of undergraduate higher education.

(e) *Public institutions of undergraduate higher education.* Subpart C does not apply to any public institution of undergraduate higher education which traditionally and continually from its establishment has had a policy of admitting only students of one sex.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

[40 FR 24128, June 4, 1975; 40 FR 39506, Aug. 28, 1975]

§ 86.16 Educational institutions eligible to submit transition plans.

(a) *Application.* This section applies to each educational institution to which Subpart C applies which:

(1) Admitted only students of one sex as regular students as of June 23, 1972; or

(2) Admitted only students of one sex as regular students as of June 23, 1965, but thereafter admitted as regular students, students of the sex not admitted prior to June 23, 1965.

(b) *Provision for transition plans.* An educational institution to which this section applies shall not discriminate on the basis of sex in admission or recruitment in violation of Subpart C unless it is carrying out a transition plan approved by the United States Commissioner of Education as described in § 86.17, which plan provides for the elimination of such discrimination by the earliest practicable date but in no event later than June 23, 1979.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.17 Transition plans.

(a) *Submission of plans.* An institution to which § 86.16 applies and which is composed of more than one administratively separate unit may submit either a single transition plan applicable to all such units, or a separate transition plan applicable to each such unit.

(b) *Content of plans.* In order to be approved by the United States Commissioner of Education, a transition plan shall:

(1) State the name, address, and Federal Interagency Committee on Education (FICE) Code of the educational institution submitting such plan, the administratively separate units to which the plan is applicable, and the name, address, and telephone number of the person to whom questions concerning the plan may be addressed. The person who submits the plan shall be the chief administrator or president of the institution, or another individual legally authorized to bind the institution to all actions set forth in the plan.

(2) State whether the educational institution or administratively separate unit admits students of both sexes, as regular students and, if so, when it began to do so.

(3) Identify and describe with respect to the educational institution or administratively separate unit any obstacles to admitting students without discrimination on the basis of sex.

(4) Describe in detail the steps necessary to eliminate as soon as practicable each obstacle so identified and indicate the schedule for taking these steps and the individual directly responsible for their implementation.

(5) Include estimates of the number of students, by sex, expected to apply for, be admitted to, and enter each class during the period covered by the plan.

(c) *Nondiscrimination.* No policy or practice of a recipient to which § 86.16 applies shall result in treatment of applicants to or students of such recipient in violation of Subpart C unless such treatment is necessitated by an obstacle identified in paragraph (b)(3) of this section and a schedule for eliminating that obstacle has been provided as required by paragraph (b)(4) of this section.

(d) *Effects of past exclusion.* To overcome the effects of past exclusion of students on the basis of sex, each educational institution to which § 86.16 applies shall include in its transition plan, and shall implement, specific steps designed to encourage individuals of the previously excluded sex to apply for admission to such institution. Such steps shall include instituting recruitment programs which emphasize the institution's commitment to enrolling students of the sex previously excluded.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

[40 FR 24128, June 4, 1975; 40 FR 39506, Aug. 28, 1975]

§§ 86.18—86.20 [Reserved]

Subpart C—Discrimination on the Basis of Sex in Admission and Recruitment Prohibited

§ 86.21 Admission.

(a) *General.* No person shall, on the basis of sex, be denied admission, or be subjected to discrimination in admission, by any recipient to which this subpart applies, except as provided in §§ 86.16 and 86.17.

(b) *Specific prohibitions.* (1) In determining whether a person satisfies any policy or criterion for admission, or in making any offer of admission, a recipient to which this Subpart applies shall not:

(i) Give preference to one person over another on the basis of sex, by ranking applicants separately on such basis, or otherwise;

(ii) Apply numerical limitations upon the number or proportion of persons of either sex who may be admitted; or

(iii) Otherwise treat one individual differently from another on the basis of sex.

(2) A recipient shall not administer or operate any test or other criterion for admission which has a disproportionately adverse effect on persons on the basis of sex unless the use of such test or criterion is shown to predict validly success in the education program or activity in question and alternative tests or criteria which do not have such a disproportionately adverse effect are shown to be unavailable.

(c) *Prohibitions relating to marital or parental status.* In determining whether a person satisfies any policy or criterion for admission, or in making any offer of admission, a recipient to which this subpart applies:

(1) Shall not apply any rule concerning the actual or potential parental, family, or marital status of a student or applicant which treats persons differently on the basis of sex;

(2) Shall not discriminate against or exclude any person on the basis of pregnancy, childbirth, termination of pregnancy, or recovery therefrom, or establish or follow any rule or practice which so discriminates or excludes;

(3) Shall treat disabilities related to pregnancy, childbirth, termination of pregnancy, or recovery therefrom in the same manner and under the same policies as any other temporary disability or physical condition; and

(4) Shall not make pre-admission inquiry as to the marital status of an applicant for admission, including whether such applicant is "Miss" or "Mrs." A recipient may make pre-admission inquiry as to the sex of an applicant for admision, but only if such inquiry is made equally of such applicants of both sexes and if the results of such inquiry are not used in connection with discrimination prohibited by this part.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.22 Preference in admission.

A recipient to which this subpart applies shall not give preference to applicants for admission, on the basis of attendance at any educational institution or other school or entity which admits as students or predominantly members of one sex, if the giving of such preference has the effect of discriminating on the basis of sex in violation of this subpart.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.23 Recruitment.

(a) *Nondiscriminatory recruitment.* A recipient to which this subpart applies shall not discriminate on the basis of sex in the recruitment and admission of students. A recipient may be required to undertake additional recruitment efforts for one sex as remedial action pursuant to § 86.3(a), and may choose to undertake such efforts as affirmative action pursuant to § 86.3(b).

(b) *Recruitment at certain institutions.* A recipient to which this subpart applies shall not recruit primarily or exclusively at educational institutions, schools or entities which admit as students only or predominantly members of one sex, if such actions have the effect of discriminating on the basis of sex in violation of this subpart.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§§ 86.24—86.30 [Reserved]

Subpart D—Discrimination on the Basis of Sex in Education Programs and Activities Prohibited

§ 86.31 Education programs and activities.

(a) *General.* Except as provided elsewhere in this part, no person shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any academic, extracurricular, research, occupational training, or other education program or activity operated by a recipient which receives of benefits from Federal financial assistance. This subpart does not apply to actions of a recipient in connection with admission of its students to an education program or activity of (1) a recipient to which Subpart C does not apply, or (2) an entity, not a recipient, to which Subpart C would not apply if the entity were a recipient.

(b) *Specific prohibitions.* Except as provided in this subpart, in providing any aid, benefit, or service to a student, a recipient shall not, on the basis of sex:

(1) Treat one person differently from another in determining whether such person satisfies any requirement or condition for the provision of such aid, benefit, or service;

(2) Provide different aid, benefits, or services or provide aid, benefits, or services in a different manner;

(3) Deny any person any such aid, benefit, or service;

(4) Subject any person to separate or different rules of behavior, sanctions, or other treatment;

(5) Discriminate against any person in the application of any rules of appearance;

(6) Apply any rule concerning the domicile or residence of a student or applicant, including eligibility for in-state fees and tuition;

(7) Aid or perpetuate discrimination against any person by providing significant assistance to any agency, organization, or person which discriminates on the basis of sex in providing any aid, benefit or service to students or employees;

(8) Otherwise limit any person in the enjoyment of any right, privilege, advantage, or opportunity.

(c) *Assistance administered by a recipient educational institution to study at a foreign institution.* A recipient educational institution may administer or assist in the administration of scholarships, fellowships, or other awards established by foreign or domestic wills, trusts, or similar legal instruments, or by acts of foreign governments and restricted to members of one sex, which are designed to provide opportunities to study abroad, and which are awarded to students who are already matriculating at or who are graduates of the recipient institution; *Provided,* a recipient educational institution which administers or assists in the administration of such scholarships, fellowship, or other awards which are restricted to members of one sex provides, or otherwise makes available reasonable opportunities for similar studies for members of the other sex. Such opportunities may be derived from either domestic or foreign sources.

(d) *Programs not operated by recipient.* (1) This paragraph applies to any recipient which requires participation by any applicant, student, or employee in any education program or activity not operated wholly by such recipient, or which facilitates, permits, or considers such participation as part of or equivalent to an education program or activity operated by such recipient, including participation in educational consortia and cooperative employment and student-teaching assignments.

(2) Such recipient;

(i) Shall develop and implement a procedure designed to assure itself that the operator or sponsor of such other education program or activity takes no action affecting any applicant, student, or employee of such recipient which this part would prohibit such recipient from taking; and

(ii) Shall not facilitate, require, permit, or consider such participation if such action occurs.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.32 Housing.

(a) *Generally.* A recipient shall not, on the basis of sex, apply different rules or regulations, impose different fees or requirements, or offer different services or benefits related to housing, except as provided in this section (including housing provided only to married students).

(b) *Housing provided by recipient.* (1) A recipient may provide separate housing on the basis of sex.

(2) Housing provided by a recipient to students of one sex, when compared to that provided to students of the other sex, shall be as a whole:

(i) Proportionate in quantity to the number of students of that sex applying for such housing; and

(ii) Comparable in quality and cost to the student.

(c) *Other housing.* (1) A recipient shall not, on the basis of sex, administer different policies or practices concerning occupancy by its students of housing other than provided by such recipient.

(2) A recipient which, through solicitation, listing, approval of housing, or otherwise, assists any agency, organization, or person in making housing available to any of its students, shall take such reasonable action as may be necessary to assure itself that such housing as is provided to students of one sex, when compared to that provided to students of the other sex, is as a whole: (i) Proportionate in quantity and (ii) comparable in quality and cost to the student. A recipient may render such assistance to any agency, organization, or person which provides all or part of such housing to students only of one sex.

(Secs. 901, 902, 907, Education Amendments of 1972, 86 Stat. 373, 374, 375; 20 U.S.C. 1681, 1682, 1686)

§ 86.33 Comparable facilities.

A recipient may provide separate toilet, locker room, and shower facilities on the basis of sex, but such facilities provided for students of one sex shall be comparable to such facilities provided for students of the other sex.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374)

§ 86.34 Access to course offerings.

A recipient shall not provide any course or otherwise carry out any of its education program or activity separately on the basis of sex, or require or refuse participation therein by any of its students on such basis, including health, physical education, industrial, business, vocational, technical, home economics, music, and adult education courses.

(a) With respect to classes and activities in physical education at the elementary school level, the recipient shall comply fully with this section as expeditiously as possible but in no event later than one year from the effective date of this regulation. With respect to physical education classes and activities at the secondary and post-secondary levels, the recipient shall comply fully with this section as expeditiously as possible but in no event later than three years from the effective date of this regulation.

(b) This section does not prohibit grouping of students in physical education classes and activities by ability as assessed by objective standards of individual performance developed and applied without regard to sex.

(c) This section does not prohibit separation of students by sex within physical education classes or activities during participation in wrestling, boxing, rugby, ice hockey, football, basketball and other sports the purpose or major activity of which involves bodily contact.

(d) Where use of a single standard of measuring skill or progress in a physical education class has an adverse effect on members of one sex, the recipient shall use appropriate standards which do not have such effect.

(e) Portions of classes in elementary and secondary schools which deal exclusively with human sexuality may be conducted in separate sessions for boys and girls.

(f) Recipients may make requirements based on vocal range or quality which may result in a chorus or choruses of one or predominantly one sex.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.35 Access to schools operated by L.E.A.s.

A recipient which is a local educational agency shall not, on the basis of sex, exclude any person from admission to:

(a) Any institution of vocational education operated by such recipient; or

(b) Any other school or educational unit operated by such recipient, unless such recipient otherwise makes available to such person, pursuant to the same policies and criteria of admission, courses, services, and facilities comparable to each course, service, and facility offered in or through such schools.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.36 Counseling and use of appraisal and counseling materials.

(a) *Counseling.* A recipient shall not discriminate against any person on the basis of sex in the counseling or guidance of students or applicants for admission.

(b) *Use of appraisal and counseling materials.* A recipient which uses testing or other materials for appraising or counseling students shall not use different materials for students on the basis of their sex or use materials which permit or require different treatment of students on such basis unless such different materials cover the same occupations and interest areas and the use of such different materials is shown to be essential to eliminate sex bias. Recipients shall develop and use internal procedures for ensuring that such materials do not discriminate on the basis of sex. Where the use of a counseling test or other instrument results in a substantially disproportionate number of members of one sex in any particular course of study or classification, the recipient shall take such action as is necessary to assure itself that such disproportion is not the result of discrimination in the instrument or its application.

(c) *Disproportion in classes.* Where a recipient finds that a particular class contains a substantially disproportionate number of individuals of one sex, the recipient shall take such action as is necessary to assure itself that such disproportion is not the result of discrimination on the basis of sex in counseling or appraisal materials or by counselors.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.37 Financial assistance.

(a) *General.* Except as provided in paragraphs (b) and (c) of this section, in providing financial assistance to any of its students, a recipient shall not: (1) On the basis of sex, provide different amount or types of such assistance, limit eligibility for such assistance which is of any particular type or source, apply different criteria, or otherwise discriminate; (2) through solicitation, listing, approval, provision of facilities or other services, assist any foundation, trust, agency, organization, or person which provides assistance to any of such recipient's students in a manner which discriminates on the basis of sex; or (3) apply any rule or assist in application of any rule concerning eligibility for such assistance which treats persons of one sex differently from persons of the other sex with regard to marital or parental status.

(b) *Financial aid established by certain legal instruments.* (1) A recipient may administer or assist in the administration of scholarships, fellowships, or other forms of financial assistance established pursuant to domestic or foreign wills, trusts, bequests, or similar legal instruments or by acts of a foreign government which requires that awards be made to members of a particular sex specified therein; *Provided,* That the overall effect of the award of such sex-restricted scholarships, fellowships, and other forms of financial assistance does not discriminate on the basis of sex.

(2) To ensure nondiscriminatory awards of assistance as required in paragraph (b)(1) of this section, recipients shall develop and use procedures under which:

(i) Students are selected for award of financial assistance on the basis of nondiscriminatory criteria and not on the basis of availability of funds restricted to members of a particular sex;

(ii) An appropriate sex-restricted scholarship, fellowship, or other form of financial assistance is allocated to each student selected under paragraph (b)(2)(i) of this section; and

(iii) No student is denied the award for which he or she was selected under paragraph (b)(2)(i) of this section because of the absence of a scholarship, fellowship, or other form of financial assistance designated for a member of that student's sex.

(c) *Athletic scholarships.* (1) To the extent that a recipient awards athletic scholarships or grants-in-aid, it must provide reasonable opportunities for such awards for members of each sex in proportion to the number of students of each sex participating in interscholastic or intercollegiate athletics.

(2) Separate athletic scholarships or grants-in-aid for members of each sex may be provided as part of separate athletic teams for members of each sex to the extent consistent with this paragraph and § 86.41.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682; and sec. 844, Education Amendments of 1974, Pub. L. 93-380, 88 Stat. 484)

[40 FR 24128, June 4, 1975; 40 FR 39506, Aug. 28, 1975]

§ 86.38 Employment assistance to students.

(a) *Assistance by recipient in making available outside employment.* A recipient which assists any agency, organization or person in making employment available to any of its students:

(1) Shall assure itself that such employment is made available without discrimination on the basis of sex; and

(2) Shall not render such services to any agency, organization, or person which discriminates on the basis of sex in its employment practices.

(b) *Employment of students by recipients.* A recipient which employs any of its students shall not do so in a manner which violates Subpart E of this part.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.39 Health and insurance benefits and services.

In providing a medical, hospital, accident, or life insurance benefit, service, policy, or plan to any of its students, a recipient shall not discriminate on the basis of sex, or provide such benefit, service, policy, or plan in a manner which would violate Subpart E of this part if it were provided to employees of the recipient. This section shall not prohibit a recipient from providing any benefit or service which may be used by a different proportion of students of one sex than of the other, including family planning services. However, any recipient which provides full coverage health service shall provide gynecological care.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.40 Marital or parental status.

(a) *Status generally.* A recipient shall not apply any rule concerning a student's actual or potential parental, family, or marital status which treats students differently on the basis of sex.

(b) *Pregnancy and related conditions.* (1) A recipent shall not discriminate against any student, or exclude any student from its education program or activity, including any class or extracurricular activity, on the basis of such student's pregnancy, childbirth, false pregnancy, termination of pregnancy or recovery therefrom, unless the student requests voluntarily to participate in a separate portion of the program or activity of the recipient.

(2) A recipient may require such a student to obtain the certification of a physician that the student is physically and emotionally able to continue participation in the normal education program or activity so long as such a certification is required of all students for other physical or emotional conditions requiring the attention of a physician.

(3) A recipient which operates a portion of its education program or activity separately for pregnant students, admittance to which is completely voluntary on the part of the student as provided in paragraph (b)(1) of this section shall ensure that the instructional program in the separate program is comparable to that offered to non-pregnant students.

(4) A recipient shall treat pregnancy, childbirth, false pregnancy, termination of pregnancy and recovery therefrom in the same manner and under the same policies as any other temporary disability with respect to any medical or hospital benefit, service, plan or policy which such recipient administers, operates, offers, or participates in with respect to students ad-

mitted to the recipient's educational program or activity.

(5) In the case of a recipient which does not maintain a leave policy for its students, or in the case of a student who does not otherwise qualify for leave under such a policy, a recipient shall treat pregnancy, childbirth, false pregnancy, termination of pregnancy and recovery therefrom as a justification for a leave of absence for so long a period of time as is deemed medically necessary by the student's physician, at the conclusion of which the student shall be reinstated to the status which she held when the leave began.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.41 Athletics.

(a) *General.* No person shall, on the basis of sex, be excluded from participation in, be denied the benefits of, be treated differently from another person or otherwise be discriminated against in any interscholastic, intercollegiate, club or intramural athletics offered by a recipient, and no recipient shall provide any such athletics separately on such basis.

(b) *Separate teams.* Notwithstanding the requirements of paragraph (a) of this section, a recipient may operate or sponsor separate teams for members of each sex where selection for such teams is based upon competitive skill or the activity involved is a contact sport. However, where a recipient operates or sponsors a team in a particular sport for members of one sex but operates or sponsors no such team for members of the other sex, and athletic opportunities for members of that sex have previously been limited, members of the excluded sex must be allowed to try-out for the team offered unless the sport involved is a contact sport. For the purposes of this part, contact sports include boxing, wrestling, rugby, ice hockey, football, basketball and other sports the purpose of major activity of which involves bodily contact.

(c) *Equal opportunity.* A recipient which operates or sponsors interscholastic, intercollegiate, club or intramural athletics shall provide equal athletic opportunity for members of both sexes. In determining whether equal opportunities are available the Director will consider, among other factors:

(1) Whether the selection of sports and levels of competition effectively accommodate the interests and abilities of members of both sexes;

(2) The provision of equipment and supplies;

(3) Scheduling of games and practice time;

(4) Travel and per diem allowance;

(5) Opportunity to receive coaching and academic tutoring;

(6) Assignment and compensation of coaches and tutors;

(7) Provision of locker rooms, practice and competitive facilities;

(8) Provision of medical and training facilities and services;

(9) Provision of housing and dining facilities and services;

(10) Publicity.

Unequal aggregate expenditures for members of each sex or unequal expenditures for male and female teams if a recipient operates or sponsors separate teams will not constitute noncompliance with this section, but the Director may consider the failure to provide necessary funds for teams for one sex in assessing equality of opportunity for members of each sex.

(d) *Adjustment period.* A recipient which operates or sponsors interscholastic, intercollegiate, club or intramural athletics at the elementary school level shall comply fully with this section as expeditiously as possible but in no event later than one year from the effective date of this regulation. A recipient which operates or sponsors interscholastic, intercollegiate, club or intramural athletics at the secondary or post-secondary school level shall comply fully with this section as expeditiously as possible but in no event later than three years from the effective date of this regulation.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682; and sec. 844, Education Amendments of 1974, Pub. L. 93-380, 88 Stat. 484)

[40 FR 24128, June 4, 1975; 40 FR 39506, Aug. 28, 1975]

§ 86.42 Textbooks and curricular material.

Nothing in this regulation shall be interpreted as requiring or prohibiting or abridging in any way the use of particular textbooks or curricular materials.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§§ 86.43—86.50 [Reserved]

Subpart E—Discrimination on the Basis of Sex in Employment in Education Programs and Activities Prohibited

§ 86.51 Employment.

(a) *General.* (1) No person shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination in employment, or recruitment, consideration, or selection therefor, whether full-time or part-time, under any education program or activity operated by a recipient which receives or benefits from Federal financial assistance.

(2) A recipient shall make all employment decisions in any education program or activity operated by such recipient in a nondiscriminatory manner and shall not limit, segregate, or classify applicants or employees in any way which could adversely affect any applicant's or employee's employment opportunities or status because of sex.

(3) A recipient shall not enter into any contractual or other relationship which directly or indirectly has the effect of subjecting employees or students to discrimination prohibited by this subpart, including relationships with employment and referral agencies, with labor unions, and with organizations providing or administering fringe benefits to employees of the recipient.

(4) A recipient shall not grant preferences to applicants for employment on the basis of attendance at any educational institution or entity which admits as students only or predominantly members of one sex, if the giving of such preferences has the effect of discriminating on the basis of sex in violation of this part.

(b) *Application.* The provisions of this subpart apply to:

(1) Recruitment, advertising, and the process of application for employment;

(2) Hiring, upgrading, promotion, consideration for and award of tenure, demotion, transfer, layoff, termination, application of nepotism policies, right of return from layoff, and rehiring;

(3) Rates of pay or any other form of compensation, and changes in compensation;

(4) Job assignments, classifications and structure, including position descriptions, lines of progression, and seniority lists;

(5) The terms of any collective bargaining agreement;

(6) Granting and return from leaves of absence, leave for pregnancy, childbirth, false pregnancy, termination of pregnancy, leave for persons of either sex to care for children or dependents, or any other leave;

(7) Fringe benefits available by virtue of employment, whether or not administered by the recipient;

(8) Selection and financial support for training, including apprenticeship, professional meetings, conferences, and other related activities, selection for tuition assistance, selection for sabbaticals and leaves of absence to pursue training;

(9) Employer-sponsored activities, including social or recreational programs; and

(10) Any other term, condition, or privilege of employment.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.52 Employment criteria.

A recipient shall not administer or operate any test or other criterion for any employment opportunity which has a disproportionately adverse effect on persons on the basis of sex unless:

(a) Use of such test or other criterion is shown to predict validly successful performance in the position in question; and

(b) Alternative tests or criteria for such purpose, which do not have such disproportionately adverse effect, are shown to be unavailable.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.53 Recruitment.

(a) *Nondiscriminatory recruitment and hiring.* A recipient shall not discriminate on the basis of sex in the recruitment and hiring of employees. Where a recipient has been found to be presently discriminating on the basis of sex in the recruitment or hiring of employees, or has been found to have in the past so discriminated, the recipient shall recruit members of the sex so discriminated against so as to overcome the effects of such past or present discrimination.

(b) *Recruitment patterns.* A recipient shall not recruit primarily or exclusively at entities which furnish as applicants only or predominantly members of one sex if such actions have the effect of discriminating on the basis of sex in violation of this subpart.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.54 Compensation.

A recipient shall not make or enforce any policy or practice which, on the basis of sex:

(a) Makes distinctions in rates of pay or other compensation;

(b) Results in the payment of wages to employees of one sex at a rate less than that paid to employees of the opposite sex for equal work on jobs the performance of which requires equal skill, effort, and responsibility, and which are performed under similar working conditions.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.55 Job classification and structure.

A recipient shall not:

(a) Classify a job as being for males or for females;

(b) Maintain or establish separate lines of progression, seniority lists, career ladders, or tenure systems based on sex; or

(c) Maintain or establish separate lines of progression, seniority systems, career ladders, or tenure systems for similar jobs, position descriptions, or job requirements which classify persons on the basis of sex, unless sex is a bona-fide occupational qualification for the positions in question as set forth in § 86.61.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

[40 FR 24128, June 4, 1975; 40 FR 39506, Aug. 28, 1975]

§ 86.56 Fringe benefits.

(a) *"Fringe benefits" defined.* For purposes of this part, "fringe benefits" means: Any medical, hospital, accident, life insurance or retirement benefit, service, policy or plan, any profit-sharing or bonus plan, leave, and any other benefit or service of employment not subject to the provision of § 86.54.

(b) *Prohibitions.* A recipient shall not:

(1) Discriminate on the basis of sex with regard to making fringe benefits available to employees or make fringe benefits available to spouses, families, or dependents of employees differently upon the basis of the employee's sex;

(2) Administer, operate, offer, or participate in a fringe benefit plan which does not provide either for equal periodic benefits for members of each sex, or for equal contributions to the plan by such recipient for members of each sex; or

(3) Administer, operate, offer, or participate in a pension or retirement plan which establishes different optional or compulsory retirement ages based on sex or which otherwise discriminates in benefits on the basis of sex.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.57 Marital or parental status.

(a) *General.* A recipient shall not apply any policy or take any employment action:

(1) Concerning the potential marital, parental, or family status of an employee or applicant for employment which treats persons differently on the basis of sex; or

(2) Which is based upon whether an employee or applicant for employment is the head of household or principal

wage earner in such employee's or applicant's family unit.

(b) *Pregnancy.* A recipient shall not discriminate against or exclude from employment any employee or applicant for employment on the basis of pregnancy, childbirth, false pregnancy, termination of pregnancy, or recovery therefrom.

(c) *Pregnancy as a temporary disability.* A recipient shall treat pregnancy, childbirth, false pregnancy, termination of pregnancy, and recovery therefrom and any temporary disability resulting therefrom as any other temporary disability for all job related purposes, including commencement, duration and extensions of leave, payment of disability income, accrual of seniority and any other benefit or service, and reinstatement, and under any fringe benefit offered to employees by virtue of employment.

(d) *Pregnancy leave.* In the case of a recipient which does not maintain a leave policy for its employees, or in the case of an employee with insufficient leave or accrued employment time to qualify for leave under such a policy, a recipient shall treat pregnancy, childbirth, false pregnancy, termination of pregnancy and recovery therefrom as a justification for a leave of absence without pay for a reasonable period of time, at the conclusion of which the employee shall be reinstated to the status which she held when the leave began or to a comparable position, without decrease in rate of compensation or loss of promotional opportunities, or any other right or privilege of employment.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.58 Effect of State or local law or other requirements.

(a) *Prohibitory requirements.* The obligation to comply with this subpart is not obviated or alleviated by the existence of any State or local law or other requirement which imposes prohibitions or limits upon employment of members of one sex which are not imposed upon members of the other sex.

(b) *Benefits.* A recipient which provides any compensation, service, or benefit to members of one sex pursuant to a State or local law or other requirement shall provide the same compensation, service, or benefit to members of the other sex.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.59 Advertising.

A recipient shall not in any advertising related to employment indicate preference, limitation, specification, or discrimination based on sex unless sex is a *bona-fide* occupational qualification for the particular job in question.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.60 Pre-employment inquiries.

(a) *Marital status.* A recipient shall not make pre-employment inquiry as to the marital status of an applicant for employment, including whether such applicant is "Miss or Mrs."

(b) *Sex.* A recipient may make pre-employment inquiry as to the sex of an applicant for employment, but only if such inquiry is made equally of such applicants of both sexes and if the results of such inquiry are not used in connection with discrimination prohibited by this part.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.61 Sex as a bona-fide occupational qualification.

A recipient may take action otherwise prohibited by this subpart provided it is shown that sex is a bona-fide occupational qualification for that action, such that consideration of sex with regard to such action is essential to successful operation of the employment function concerned. A recipient shall not take action pursuant to this section which is based upon alleged comparative employment characteristics or stereotyped characterizations of one or the other sex, or upon preference based on sex of the recipient, employees, students, or other persons, but nothing contained in this section shall prevent a recipient from considering an employee's sex in relation to employment in a locker room or toilet facility used only by members of one sex.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§§ 86.62—86.70 [Reserved]

Subpart F—Procedures [Interim]

§ 86.71 Interim procedures.

For the purposes of implementing this part during the period between its effective date and the final issuance by the Department of a consolidated procedural regulation applicable to title IX and other civil rights authorities administered by the Department, the procedural provisions applicable to title VI of the Civil Rights Act of 1964 are hereby adopted and incorporated herein by reference. These procedures may be found at 45 CFR 80-6 through 80-11 and 45 CFR Part 81.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

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APPENDIX A—GUIDELINES FOR ELIMINATING DISCRIMINATION AND DENIAL OF SERVICES ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, SEX, AND HANDICAP IN VOCATIONAL EDUCATION PROGRAMS

EDITORIAL NOTE: For the text of these guidelines, see 45 CFR Part 80, Appendix B.

[44 FR 17168, Mar. 21, 1979]

PART 90—NONDISCRIMINATION ON THE BASIS OF AGE IN PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE

Subpart A—General

Sec.

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90.2 What is the purpose of these regulations?
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Subpart E—Future Review of Age Discrimination Regulations

90.61 Review of general regulations.
90.62 Review of agency regulations.

AUTHORITY: Age Discrimination Act of 1975, 42 U.S.C. 6101 et seq.

SOURCE: 44 FR 33776, June 12, 1979, unless otherwise noted.

Subpart A—General

§ 90.1 What is the purpose of the Age Discrimination Act of 1975?

The Age Discrimination Act of 1975, as amended, is designed to prohibit discrimination on the basis of age in programs or activities receiving Federal financial assistance. The Act also permits federally assisted programs and activities, and recipients of Federal funds, to continue to use certain age distinctions and factors other than age which meet the requirements of the Act and these regulations.

§ 90.2 What is the purpose of these regulations?

(a) The purpose of these regulations is to state general, government-wide rules for the implementation of the Age Discrimination Act of 1975, as amended, and to guide each agency in the preparation of agency-specific age discrimination regulations.

(b) These regulations apply to each Federal agency which provides Federal financial assistance to any program or activity.

§ 90.3 What programs and activities does the Age Discrimination Act of 1975 cover?

(a) The Age Discrimination Act of 1975 applies to any program or activity receiving Federal financial assistance, including programs or activities receiving funds under the State and Local Fiscal Assistance Act of 1972 (31 U.S.C. 1221 *et seq.*).

(b) The Age Discrimination Act of 1975 does not apply to:

(1) An age distinction contained in that part of a Federal, State of local statute or ordinance adopted by an elected, general purpose legislative body which:

(i) Provides any benefits or assistance to persons based on age; or

(ii) Establishes criteria for participation in age-related terms; or

(iii) Describes intended beneficiaries or target groups in age-related terms.

(2) Any employment practice of any employer, employment agency, labor organization, or any labor-management joint apprenticeship training program, except for any program or activity receiving Federal financial assistance for public service employment under the Comprehensive Employment and Training Act of 1974 (CETA), (29 U.S.C. 801 *et seq.*).

§ 90.4 How are the terms in these regulations defined?

As used in these regulations, the term:

"Act" means the Age Discrimination Act of 1975, as amended, (Title III of Pub. L. 94-135).

"Action" means any act, activity, policy, rule, standard, or method of administration; or the use of any policy, rule, standard, or method of administration.

"Age" means how old a person is, or the number of elapsed years form the date of a person's birth.

"Age distinction" means any action using age or an age-related term.

"Age-related term" means a word or words which necessarily imply a particular age or range of ages (for example, "children," "adult," "older persons," but not "student").

"Agency" means a Federal department or agency that is empowered to extend financial assistance.

"Federal financial assistance" means any grant, entitlement, loan, cooperative agreement, contract (other than a procurement contract or a contract of insurance or guaranty), or any other arrangement by which the agency provides or otherwise makes available assistance in the form of:

(a) Funds;

(b) Services of Federal personnel; or

(c) Real and personal property or any interest in or use of property, including:

(1) Transfers or leases of property for less than fair market value or for reduced consideration; and

(2) Proceeds from a subsequent transfer or lease of property if the Federal share of its fair market value is not returned to the Federal Government.

"Recipient" means any State or its political subdivision, any instrumentality of a State or its political sub-division, any public or private agency, institution, organization, or other entity, or any person to which Federal financial assistance is extended, directly or through another recipient. Recipient includes any successor, assignee, or transferee, but excludes the ultimate beneficiary of the assistance.

"Secretary" means the Secretary of the Department of Health and Human Services.

"United States" means the fifty States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, Wake Island, the Canal Zone, the Trust Territory of the Pacific Islands, the Northern Marianas, and the territories and possessions of the United States.

Subpart B—What is Age Discrimination?

STANDARDS FOR DETERMINING DISCRIMINATORY PRACTICES

§ 90.11 Purpose of this subpart.

The purpose of this subpart is to set forth the prohibitions against age discrimination and the exceptions to those prohibitions.

§ 90.12 Rules against age discrimination.

The rules stated in this section are limited by the exceptions contained in §§ 90.14, and 90.15 of these regulations.

(a) *General rule:* No person in the United states shall, on the basis of age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity receiving Federal financial assistance.

(b) *Specific rules:* A recipient may not, in any program or activity receiving Federal financial assistance, directly or through contractual, licensing, or other arrangements use age distinctions or take any other actions which have the effect, on the basis of age, of:

(1) Excluding individuals from, denying them the benefits of, or subjecting them to discrimination under, a program or activity receiving Federal financial assistance, or

(2) Denying or limiting individuals in their opportunity to participate in any program or activity receiving Federal financial assistance.

(c) The specific forms of age discrimination listed in paragraph (b) of this section do not necessarily constitute a complete list.

§ 90.13 Definitions of "normal operation" and "statutory objective."

For purposes of §§ 90.14, and 90.15, the terms "normal operation" and "statutory objective" shall have the following meaning:

(a) "Normal operation" means the operation of a program or activity without significant changes that would impair its ability to meet its objectives.

(b) "Statutory objective" means any purpose of a program or activity expressly stated in any Federal statute, State statute, or local statute or ordinance adopted by an elected, general purpose legislative body.

§ 90.14 Exceptions to the rules against age discrimination. Normal operation or statutory objective of any program or activity.

A recipient is permitted to take an action, otherwise prohibited by § 90.12, if the action reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity. An action reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity, if:

(a) Age is used as a measure or approximation of one or more other characteristics; and

(b) The other characteristic(s) must be measured or approximated in order for the normal operation of the program or activity to continue, or to achieve any statutory objective of the program or activity; and

(c) The other characteristic(s) can be reasonably measured or approximated by the use of age; and

(d) The other characteristic(s) are impractical to measure directly on an individual basis.

§ 90.15 Exceptions to the rules against age discrimination. Reasonable factors other than age.

A recipient is permitted to take an action otherwise prohibited by § 90.12 which is based on a factor other than age, even though that action may have a disproportionate effect on persons of different ages. An action may be based on a factor other than age only if the factor bears a direct and substantial relationship to the normal operation of the program or activity or to the achievement of a statutory objective.

§ 90.16 Burden of proof.

The burden of proving that an age distinction or other action falls within the exceptions outlined in §§ 90.14 and 90.15 is on the recipient of Federal financial assistance.

Subpart C—What are the Responsibilities of the Federal Agencies?

§ 90.31 Issuance of regulations.

(a) The head of each agency which extends Federal financial assistance to any program or activity shall publish proposed and final age discrimination regulations in the FEDERAL REGISTER to:

(1) Carry out the provisions of section 303 of the Age Discrimination Act of 1975; and

(2) Provide for appropriate investigative, conciliation, and enforcement procedures.

(b) Each agency shall publish its proposed agency age discrimination regulations no later than 90 days after the publication date of the final general, government-wide age discrimination regulations.

(c) Each agency shall submit its final agency regulations to HHS for review no later than 120 days after publication of proposed agency age discrimination regulations.

(d) Final agency age discrimination regulations shall be consistent with these general, government-wide age discrimination regulations and shall not be published until the Secretary approves them.

(e) Each agency shall include in its regulations a provision governing the operation of an alternate funds disbursal procedure as described in § 90.48 of these regulations.

(f) Each agency shall publish an appendix to its final age discrimination regulations containing a list of each age distinction provided in a Federal statute or in regulations affecting financial assistance administered by the agency.

§ 90.32 Review of agency policies and administrative practices.

(a) Each agency shall conduct a review of age distinctions it imposes on its recipients by regulations, policies, and administrative practices. The purpose of this review is to identify how age distinctions are used by each Federal agency and whether those age distinctions are permissible under the Act and implementing regulations.

(b) No later than 12 months from the date the agency published its final regulations, the agency shall publish, for public comment, a report in the FEDERAL REGISTER containing:

(1) The results of the review conducted under paragraph (a) of this section;

(2) A list of the age distinctions contained in regulations which are to be continued;

(3) The justification under the requirements of the Act and these regulations for each age distinction to be continued;

(4) A list of the age distinctions not contained in regulations but which will be adopted by regulation under the Administrative Procedure Act using the notice and comment procedures specified in 5 U.S.C. 553; and

(5) A list of the age distinctions to be eliminated.

(c) Beginning with the effective date of an agency's final regulations, the agency may not impose a new age distinction unless the age distinction is adopted by regulation under the Administrative Procedure Act using the notice and comment procedures specified in 5 U.S.C. 553.

(d) Beginning 12 months after the publication of its age discrimination regulations, an agency may not continue an existing age distinction, unless the age distinction has already been adopted by regulation or is adopted by regulation under the Administrative Procedure Act using the notice and comment procedures specified in 5 U.S.C. 553.

§ 90.33 Interagency cooperation.

Where two or more agencies provide Federal financial assistance to a recipient or class of recipients, the Secretary may designate one of the agencies as the sole agency for all compliance and enforcement purposes with respect to those recipients, except for the ordering of termination of funds and the notification of the appropriate committees of Congress.

§ 90.34 Agency reports.

Each agency shall submit to the Secretary not later than December 31 of each year, beginning in 1979, a report which:

(a) Describes in detail the steps taken during the preceding fiscal year to carry out the Act; and

(b) Contains data on the frequency, type, and resolution of complaints and on any compliance reviews, sufficient to permit analysis of the agency's progress in reducing age discrimination in programs receiving Federal financial assistance from the agency; and

(c) Contains data directly relevant to the extent of any pattern or practice of age discrimination which the agency has identified in any programs receiving Federal financial assistance from the agency and to progress toward eliminating it; and

(d) Contains evaluative or interpretative information which the agency determines is useful in analyzing agency progress in reducing age discrimination in programs receiving Federal financial assistance from the agency; and

(e) Contains whatever other data the Secretary may require.

Subpart D—Investigation, Conciliation and Enforcement Procedures

§ 90.41 What is the purpose of this subpart?

This subpart sets forth requirements for the establishment of compliance, investigation, conciliation, and enforcement procedures by agencies which extend Federal financial assistance.

§ 90.42 What responsibilities do recipients and agencies have generally to ensure compliance with the Act?

(a) A recipient has primary responsibility to ensure that its programs and activities are in compliance with the Age Discrimination Act and shall take steps to eliminate violations of the Act. A recipient also has responsibility to maintain records, provide information, and to afford access to its records to an agency to the extent required to determine whether it is in compliance with the Act.

(b) An agency has responsibility to attempt to secure recipient compliance with the Act by voluntary means. This may include the use of the services of appropriate Federal, State, local, or private organizations. An agency also has the responsibility to enforce the Age Discrimination Act when a recipient fails to eliminate violations of the Act.

§ 90.43 What specific responsibilities do agencies and recipients have to ensure compliance with the Act?

(a) *Written notice, technical assistance, and educational materials.* Each agency shall: (1) Provide written notice to each recipient of its obligations under the Act. The notice shall include a requirement that where the recipient initially receiving funds makes the funds available to a sub-recipient, the recipient must notify the sub-recipient of its obligations under the Act.

(2) Provide technical assistance, where necessary, to recipients to aid them in complying with the Act.

(3) Make available educational materials setting forth the rights and obligations of beneficiaries and recipients under the Act.

(b) *Self-evaluation.* (1) Each agency shall require each recipient employing the equivalent of 15 or more full time employees to complete a written self-evaluation of its compliance under the Act within 18 months of the effective date of the agency regulations.

(2) Each recipient's self-evaluation shall identify and justify each age distinction imposed by the recipient.

(3) Each recipient shall take corrective and remedial action whenever a self-evaluation indicates a violation of the Act.

(4) Each recipient shall make the self-evaluation available on request to the agency and to the public for a period of 3 years following its completion.

(c) *Complaints*—(1) *Receipt of complaints.* Each agency shall establish a complaint processing procedure which includes the following:

(i) A procedure for the filing of complaints with the agency;

(ii) A review of complaints to assure that they fall within the coverage of the Act and contain all information necessary for further processing;

(iii) Notice to the complainant and the recipient of their rights and obligations under the complaint procedure, including the right to have a representative at all stages of the complaint procedure; and

(iv) Notice to the complainant and the recipient (or their representatives) of their right to contact the agency for information and assistance regarding the complaint resolution process.

(2) *Prompt resolution of complaints.* Each agency shall establish procedures for the prompt resolution of complaints. These procedures shall require each recipient and complainant to participate actively in efforts toward speedy resolution of the complaint.

(3) *Mediation of complaints.* Each agency shall promptly refer all complaints which fall within the coverage of the Act to a mediation agency designated by the Secretary.

(i) The referring agency shall require the participation of the recipient and the complainant in the mediation process, although both parties need not meet with the mediator at the same time.

(ii) If the complainant and recipient reach a mutually satisfactory resolution of the complaint during the mediation period, they shall reduce the agreement to writing. The mediator shall send a copy of the settlement to the referring agency. No further action shall be taken based on that complaint unless it appears that the complainant or the recipient is failing to comply with the agreement.

(iii) Not more than 60 days after the agency receives the complaint, the mediator shall return a still unresolved complaint to the referring agency for initial investigation. The mediator may return a complaint at any time before the end of the 60 day period if it appears that the complaint cannot be resolved through mediation.

(iv) The mediator shall protect the confidentiality of all information obtained in the course of the mediation process. No mediator shall testify in any adjudicative proceeding, produce any document, or otherwise disclose any information obtained in the course of the mediation process without prior approval of the head of the agency appointing the mediator.

(4) *Federal initial investigation.* Each agency shall investigate complaints unresolved after mediation or reopened because of a violation of the mediation agreement. As part of the initial investigation, the agency shall use informal fact finding methods including joint or individual discussions with the complainant and the recipient to establish the facts, and, if possible, resolve the complaint to the mutual satisfaction of the parties. The agency may seek the assistance of any involved State program agency.

(5) *Formal investigation, conciliation, and hearing.* If the agency cannot resolve the complaint during the early stages of the investigation, it shall:

(i) Complete the investigation of the complaint.

(ii) Attempt to achieve voluntary compliance satisfactory to the agency, if the investigation indicates a violation.

(iii) Arrange for enforcement as described in § 90.47, if necessary.

§ 90.44 Compliance reviews.

(a) Each agency shall provide in its regulations that it may conduct compliance reviews, pre-award reviews, and other similar procedures which permit the agency to investigate, and correct, violations of the Act without regard to its procedures for handling complaints.

(b) If a compliance review or pre-award review indicates a violation of the Act, the agency shall attempt to achieve voluntary compliance with the Act. If voluntary compliance cannot be achieved, the agency shall arrange for enforcement as described in § 90.47.

§ 90.45 Information requirements.

Each agency shall provide in its regulations a requirement that the recipient:

(a) Provide to the agency information necessary to determine whether the recipient is in compliance with the Act; and

(b) Permit reasonable access by the agency to the books, records, accounts, and other recipient facilities and sources of information to the extent necessary to determine whether a recipient is in compliance with the Act.

§ 90.46 Prohibition against intimidation or retaliation.

Each agency shall provide in its regulations that recipients may not engage in acts of intimidation or retaliation against any person who:

(a) Attempts to assert a right protected by the Act; or

(b) Cooperates in any mediation, investigation, hearing, or other part of the agency's investigation, conciliation, and enforcement process.

§ 90.47 What further provisions must an agency make in order to enforce its regulations after an investigation indicates that a violation of the act has been committed?

(a) Each agency shall provide for enforcement of its regulations through:

(1) Termination of a recipient's Federal financial assistance under the program or activity involved where the recipient has violated the Act or the agency's regulations. The determination of the recipient's violation may be made only after a recipient has had an opportunity for a hearing on the record before an administrative law judge.

(2) Any other means authorized by law including but not limited to:

(i) Referral to the Department of Justice for proceedings to enforce any rights of the United States or obligations of the recipient created by the Act or the agency's regulations.

(ii) Use of any requirement of or referral to any Federal, State, or local government agency which will have the effect of correcting a violation of the Act or implementing regulations.

(b) Any termination under paragraph (a)(1) shall be limited to the particular recipient and particular program or activity receiving Federal financial assistance or portion thereof found to be in violation of the Act or agency regulations. No termination shall be based in whole or in part on a finding with respect to any program or activity which does not receive Federal financial assistance.

(c) No action under paragraph (a) of this section may be taken until:

(1) The head of the agency involved has advised the recipient of its failure to comply with the Act or the agency's regulations and has determined that voluntary compliance cannot be obtained.

(2) Thirty days have elapsed after the head of the agency involved has sent a written report of the circumstances and grounds of the action to the committees of the Congress having legislative jurisdiction over the Federal program or activity involved. A report shall be filed whenever any action is taken under paragraph (a) of this section.

(d) An agency may defer granting new Federal financial assistance to a recipient when termination proceedings under paragraph (a)(1) of this section are initiated.

(1) New Federal financial assistance includes all assistance administered by or through the agency for which an application or approval, including renewal or continuation of existing activities, or authorization of new activities, is required during the deferral period. New Federal financial assistance does not include assistance approved prior to the beginning of termination proceedings or to increases in funding as a result of changed computation of formula awards.

(2) A deferral may not begin until the recipient has received a notice of opportunity for a hearing under paragraph (a)(1). A deferral may not continue for more than 60 days unless a hearing has begun within that time or the time for beginning the hearing has been extended by mutual consent of the recipient and the agency. A deferral may not continue for more than 30 days after the close of the hearing, unless the hearing results in a finding against the recipient.

§ 90.48 Alternate funds disbursal procedure.

When an agency withholds funds from a recipient under its regulations issued under § 90.31, the head of the agency may disburse the withheld funds so directly to any public or nonprofit private organization or agency, or State or political subdivision of the State. These alternate recipients must demonstrate the ability to comply with the agency's regulations issued under this Act and to achieve the goals of the Federal statute authorizing the program or activity.

§ 90.49 Remedial and affirmative action by recipients.

(a) Where a recipient is found to have discriminated on the basis of age, the recipient shall take any remedial action which the agency may require to overcome the effects of the discrimination. If another recipient exercises control over the recipient that has discriminated, both recipients may be required to take remedial action.

(b) Even in the absence of a finding of discrimination, a recipient may take affirmative action to overcome the effects of conditions that resulted in limited participation in the recipient's program or activity on the basis of age.

(c) If a recipient operating a program which serves the elderly or children in addition to persons of other ages, provides special benefits to the elderly or to children the provision of those benefits shall be presumed to be voluntary affirmative action provided that it does not have the effect of excluding otherwise eligible persons from participation in the program.

§ 90.50 Exhaustion of administrative remedies.

(a) The agency shall provide in its regulations that a complainant may file a civil action following the exhaustion of adminstrative remedies under the Act. Administrative remedies are exhausted if:

(1) 180 days have elapsed since the complainant filed the complaint and the agency has made no finding with regard to the complaint; or

(2) The agency issues any finding in favor of the recipient.

(b) If either of the conditions set forth in § 90.50(a) is satisfied the agency shall:

(1) Promptly advise the complainant of this fact; and

(2) Advise the complainant of his or her right, under section 305(e) of the Act, to bring a civil action for injunctive relief that will effect the purposes of the Act; and

(3) Inform the complainant:

(i) That a civil action can only be brought in a United States district court for the district in which the recipient is found or transacts business;

(ii) That a complainant prevailing in a civil action has the right to be awarded the costs of the action, including reasonable attorney's fees, but that these costs must be demanded in the complaint;

(iii) That before commencing the action the complainant shall give 30 days notice by registered mail to the Secretary, the Attorney General of the United States, the head of the granting agency, and the recipient;

(iv) That the notice shall state: the alleged violation of the Act; the relief requested; the court in which the action will be brought; and whether or not attorney's fees are demanded in the event the complainant prevails; and

(v) That no action shall be brought if the same alleged violation of the Act by the same recipient is the subject of a pending action in any court of the United States.

Subpart E—Future Review of Age Discrimination Regulations

§ 90.61 Review of general regulations.

The Secretary shall review the effectiveness of these regulations in securing compliance with the Act. As part of this review, 30 months after the effective date of these regulations, the Secretary shall publish a notice of opportunity for public comment on the effectiveness of the regulations. The Secretary will assess the comments and publish the results of the review and assessment in the FEDERAL REGISTER.

§ 90.62 Review of agency regulations.

Each agency shall review the effectiveness of its regulations in securing compliance with the Act. As part of this review, 30 months after the effective date of its regulations, each agency shall publish a notice of opportunity for public comment on the effectiveness of the agency regulations. Each agency shall assess the comments and publish the results of the review in the FEDERAL REGISTER.

PART 91—NONDISCRIMINATION ON THE BASIS OF AGE IN HHS PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE

Subpart A—General

Sec.

91.1 What is the purpose of the Age Discrimination Act of 1975?
91.2 What is the purpose of HHS' age discrimination regulations?
91.3 To what programs do these regulations apply?
91.4 Definitions of terms used in these regulations.

Subpart B—Standards for Determining Age Discrimination

91.11 Rules against age discrimination.
91.12 Definitions of "normal operation" and "statutory objective".
91.13 Exceptions to the rules against age discrimination: Normal operation or statutory objective of any program or activity.
91.14 Exceptions to the rules against age discrimination: Reasonable factors other than age.
91.15 Burden of proof.
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Subpart C—Duties of HHS Recipients

91.31 General responsibilities.
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91.41 Compliance reviews.
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91.44 Investigation.
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91.47 Hearings, decisions, post-termination proceedings.
91.48 Remedial action by recipient.
91.49 Alternate funds disbursal procedure.
91.50 Exhaustion of administrative remedies.

AUTHORITY: Age Discrimination Act of 1975, as amended, 42 U.S.C. 6101 *et seq.* (45 CFR Part 90).

SOURCE: 47 FR 57858, Dec. 28, 1982, unless otherwise noted.

Subpart A—General

§ 91.1 What is the purpose of the Age Discrimination Act of 1975?

The Age Discrimination Act of 1975, as amended, is designed to prohibit discrimination on the basis of age in programs or activities receiving Federal financial assistance. The Act also permits federally assisted programs and activities, and recipients of Federal funds, to continue to use certain age distinctions and factors other than age which meet the requirements of the Act and these regulations.

§ 91.2 What is the purpose of HHS' age discrimination regulations?

The purpose of these regulations is to set out HHS' policies and procedures under the Age Discrimination Act of 1975 and the general age discrimination regulations at 45 CFR Part 90.[1] The Act and the general regulations prohibit discrimination on the basis of age in programs or activities receiving Federal financial assistance. The Act and the general regulations permit federally assisted programs and activities, and recipients of Federal funds, to continue to use age distinctions and factors other than age which meet the requirements of the Act and its implementing regulations.

§ 91.3 To what programs do these regulations apply?

(a) The Act and these regulations apply to each HHS recipient and to each program or activity operated by the recipient which receives or benefits from Federal financial assistance provided by HHS.

(b) The Act and these regulations do not apply to:

(1) An age distinction contained in that part of a Federal, State, or local statute or ordinance adopted by an elected, general purpose legislative body which:

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[1] Published at 44 FR 33768, June 12, 1979.

(i) Provides any benefits or assistance to persons based on age; or

(ii) Establishes criteria for participation in age-related terms; or

(iii) Describes intended beneficiaries or target groups in age-related terms.

(2) Any employment practice of any employer, employment agency, labor organization, or any labor-management joint apprenticeship training program, except for any program or activity receiving Federal financial assistance for public service employment under the Comprehensive Employment and Training Act (CETA), (29 U.S.C. 801 et seq.)

§ 91.4 Definition of terms used in these regulations.

As used in these regulations, the term: "Act" means the Age Discrimination Act of 1975, as amended, (Title III of Pub. L. 94-135).

"Action" means any act, activity, policy, rule, standard, or method of administration; or the use of any policy, rule, standard, or method of admininstration.

"Age" means how old a person is, or the number of years from the date of a person's birth.

"Age distinction" means any action using age or an age-related term.

"Age-related term" means a word or words which necessarily imply a particular age or range of ages (for example, "children," "adult," "older persons," but not "student").

"Agency" means a Federal department or agency that is empowered to extend financial assistance.

"Federal financial assistance" means any grant, entitlement, loan, cooperative agreement, contract (other than a procurement contract or a contract of insurance or guaranty), or any other arrangement by which the agency provides or otherwise makes available assistance in the form of:

(a) Funds; or

(b) Services of Federal personnel; or

(c) Real and personal property or any interest in or use of property, including:

(1) Transfers or leases of property for less than fair market value or for reduced consideration; and

(2) Proceeds from a subsequent transfer or lease of property if the Federal share of its fair market value is not returned to the Federal Government.

"HHS" means the United States Department of Health and Human Services.

"Recipient" means any State or its political subdivision, any instrumentality of a State or its political subdivision, any public or private agency, institution, organization, or other entity, or any person to which Federal financial assistance is extended, directly or through another recipient. Recipient includes any successor, assignee, or transferee, but excludes the ultimate beneficiary of the assistance.

"Secretary" means the Secretary of Health and Human Services, or his or her designee.

"Subrecipient" means any of the entities in the definition of "recipient" to which a recipient extends or passes on Federal financial assistance. A subrecipient is generally regarded as a recipient of Federal financial assistance and has all the duties of a recipient in these regulations.

"United States" means the fifty States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, Wake Island, the Canal Zone, the Trust Territory of the Pacific Islands, the Northern Marianas, and the territories and possessions of the United States.

Subpart B—Standards for Determining Age Discrimination

§ 91.11 Rules against age discrimination.

The rules stated in this section are limited by the exceptions contained in §§ 91.13 and 91.14 of these regulations.

(a) General rule: No person in the United States shall, on the basis of age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity receiving Federal financial assistance.

(b) Specific rules: A recipient may not, in any program or activity receiving Federal financial assistance, directly or through contractual licensing, or other arrangements, use age distinctions or take any other actions which have the effect, on the basis of age, of:

(1) Excluding individuals from, denying them the benefits of, or subjecting them to discrimination under, a program or activity receiving Federal financial assistance; or

(2) Denying or limiting individuals in their opportunity to participate in any program or activity receiving Federal financial assistance.

(c) The specific forms of age discrimination listed in paragraph (b) of this section do not necessarily constitute a complete list.

§ 91.12 Definitions of "normal operation" and "statutory objective".

For purposes of §§ 91.13 and 91.14, the terms "normal operation" and "statutory objective" shall have the following meaning:

(a) "Normal operation" means the operation of a program or activity without significant changes that would impair its ability to meet its objectives.

(b) "Statutory objective" means any purpose of a program or activity expressly stated in any Federal statute, State statute, or local statute or ordinance adopted by an elected, general purpose legislative body.

§ 91.13 Exceptions to the rules against age discrimination: Normal operation or statutory objective of any program or activity.

A recipient is permitted to take an action, otherwise prohibited by § 91.11, if the action reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity. An action reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity, if:

(a) Age is used as a measure or approximation of one or more other characteristics; and

(b) The other characteristic(s) must be measured or approximated in order for the normal operation of the program or activity to continue, or to achieve any statutory objective of the program or activity; and

(c) The other characteristic(s) can be reasonably measured or approximated by the use of age; and

(d) The other characteristic(s) are impractical to measure directly on an individual basis.

§ 91.14 Exceptions to the rules against age discrimination: Reasonable factors other than age.

A recipient is permitted to take an action otherwise prohibited by § 91.11 which is based on a factor other than age, even though that action may have a disproportionate effect on persons of different ages. An action may be based on a factor other than age only is the factor bears a direct and substantial relationship to the normal operation of the program or activity or to the achievement of a statutory objective.

§ 91.15 Burden of proof.

The burden of proving that an age distinction or other action falls within the exceptions outlined in §§ 91.13 and 91.14 is on the recipient of Federal financial assistance.

§ 91.16 Affirmative action by recipient.

Even in the absence of a finding of discrimination, a recipient may take affirmative action to overcome the effects of conditions that resulted in limited participation in the recipient's program or activity on the basis of age.

§ 91.17 Special benefits for children and the elderly.

If a recipient operating a program provides special benefits to the elderly or to children, such use of age distinctions shall be presumed to be necessary to the normal operation of the program, notwithstanding the provisions of § 91.13.

§ 91.18 Age distinctions contained in HHS regulations.

Any age distinctions contained in a rule or regulation issued by HHS shall be presumed to be necessary to the achievement of a statutory objective of the program to which the rule or regulation applies, notwithstanding the provisions of § 91.13.

Subpart C—Duties of HHS Recipients

§ 91.31 General responsibilities.

Each HHS recipient has primary responsibility to ensure that its programs and activities are in compliance with the Act and these regulations, and shall take steps to eliminate violations of the Act. A recipient also has responsibility to maintain records, provide information, and to afford HHS access to its records to the extent HHS finds necessary to determine whether the recipient is in compliance with the Act and these regulations.

§ 91.32 Notice to subrecipients and beneficiaries.

(a) Where a recipient passes on Federal financial assistance from HHS to subrecipients, the recipient shall provide the subrecipients written notice of their obligations under the Act and these regulations.

(b) Each recipient shall make necessary information about the Act and these regulations available to its program beneficiaries in order to inform them about the protections against discrimination provided by the Act and these regulations.

§ 91.33 Assurance of compliance and recipient assessment of age distinctions.

(a) Each recipient of Federal financial assistance from HHS shall sign a written assurance as specified by HHS that it will comply with the Act and these regulations.

(b) *Recipient assessment of age distinctions.* (1) As part of a compliance review under § 91.41 or complaint investigation under § 91.44, HHS may require a recipient employing the equivalent of 15 or more employees to complete a written self-evaluation, in a manner specified by the responsible Department official, of any age distinction imposed in its program or activity receiving Federal financial assistance from HHS to assess the recipient's compliance with the Act.

(2) Whenever an assessment indicates a violation of the Act and the HHS regulations, the recipient shall take corrective action.

§ 91.34 Information requirements.

Each recipient shall:

(a) Keep records in a form and containing information which HHS determines may be necessary to ascertain whether the recipient is complying with the Act and these regulations.

(b) Provide to HHS, upon request, information and reports which HHS determines are necessary to ascertain whether the recipient is complying with the Act and these regulations.

(c) Permit reasonable access by HHS to the books, records, accounts, and other recipient facilities and sources of information to the extent HHS determines is necessary to ascertain whether the recipient is complying with the Act and these regulations.

Subpart D—Investigation, Conciliation, and Enforcement Procedures

§ 91.41 Compliance reviews.

(a) HHS may conduct compliance reviews and pre-award reviews or use other similar procedures that will permit it to investigate and correct violations of the Act and these regulations. HHS may conduct these reviews even in the absence of a complaint against a recipient. The reviews may be as comprehensive as necessary to determine whether a violation of the Act and these regulations has occurred.

(b) If a compliance review or preaward review indicates a violation of the Act or these regulations, HHS will attempt to achieve voluntary compliance with the Act. If voluntary compliance cannot be achieved, HHS will arrange for enforcement as decribed in § 91.46.

§ 91.42 Complaints.

(a) Any person, individually or as a member of a class or on behalf of others, may file a complaint with HHS, alleging discrimination prohibited by the Act or these regulations based on an action occurring on or after July 1, 1979. A complainant shall file a complaint within 180 days from the date the complainant first had knowledge of the alleged act of discrimination. However, for good cause shown, HHS may extend this time limit.

(b) HHS will consider the date a complaint is filed to be the date upon which the complaint is sufficent to be processed.

(c) HHS will attempt to facilitate the filing of complaints wherever possible, including taking the following measures:

(1) Accepting as a sufficient complaint, any written statement which identifies the parties involved and the date the complainant first had knowledge of the alleged violation, describes generally the action or practice complained of, and is signed by the complainant.

(2) Freely permitting a complainant to add information to the complaint to meet the requirements of a sufficient complaint.

(3) Notifying the complainant and the recipient of their rights and obligations under the complaint procedure, including the right to have a representative at all stages of the complaint procedure.

(4) Notifying the complainant and the recipient (or their representatives) of their right to contact HHS for information and assistance regarding the complaint resolution process.

(d) HHS will return to the complainant any complaint outside the jurisdiction of these regulations, and will state the reason(s) why it is outside the jurisdiction of these regulations.

§ 91.43 Mediation.

(a) HHS will promptly refer to a mediation agency designated by the Secretary all sufficient complaints that:

(1) Fall within the jurisdiction of the Act and these regulations, unless the age distinction complained of is clearly within an exception; and,

(2) Contain all information necessary for further processing.

(b) Both the complainant and the recipient shall participate in the mediation process to the extent necessary to reach an agreement or make an informed judgment that an agreement is not possible.

(c) If the complainant and the recipient reach an agreement, the mediator shall prepare a written statement of the agreement and have the complainant and the recipient sign it. The mediator shall send a copy of the agreement to HHS. HHS will take no further action on the complaint unless the complainant or the recipient fails to comply with the agreement.

(d) The mediator shall protect the confidentiality of all information obtained in the course of the mediation process. No mediator shall testify in any adjudicative proceeding, produce any document, or otherwise disclose any information obtained in the course of the mediation process without prior approval of the head of the mediation agency.

(e) The mediation will proceed for a maximum of 60 days after a complaint is filed with HHS. Mediation ends if:

(1) 60 days elapse from the time the complaint is filed; *or*

(2) Prior to the end of that 60-day period, an agreement is reached; *or*

(3) Prior to the end of that 60-day period, the mediator determines that an agreement cannot be reached.

This 60-day period may be extended by the mediator, with the concurrence of HHS, for not more than 30 days if the mediator determines that agreement will likely be reached during such extended period.

(f) The mediator shall return unresolved complaints to HHS.

§ 91.44 Investigation.

(a) *Informal investigation.* (1) HHS will investigate complaints that are unresolved after mediation or are reopened because of a violation of a mediation agreement.

(2) As part of the initial investigation HHS will use informal fact finding methods, including joint or separate discussions with the complainant and recipient, to establish the fact and, if possible, settle the complaint on terms that are mutually agreeable to the parties. HHS may seek the assistance of any involved State program agency.

(3) HHS will put any agreement in writing and have it signed by the parties and an authorized official at HHS.

(4) The settlement shall not affect the operation of any other enforcement effort of HHS, including compliance reviews and investigation of other complaints which may involve the recipient.

(5) The settlement is not a finding of discrimination against a recipient.

(b) *Formal investigation.* If HHS cannot resolve the complaint through informal investigation, it will begin to develop formal findings through further investigation of the complaint. If the investigation indicates a violation of these regulations HHS will attempt to obtain voluntary compliance. If HHS cannot obtain voluntary compliance it will begin enforcement as described in § 91.46.

§ 91.45 Prohibition against intimidation or retaliation.

A recipient may not engage in acts of intimidation or retaliation against any person who:

(a) Attempts to assert a right protected by the Act or these regulations; or

(b) Cooperates in any mediation, investigation, hearing, or other part of HHS' investigation, conciliation, and enforcement process.

§ 91.46 Compliance procedure.

(a) HHS may enforce the Act and these regulations through:

(1) Termination of a recipient's Federal financial assistance from HHS under the program or activity involved where the recipient has violated the Act or these regulations. The determination of the recipient's violation may be made only after a recipient has had an opportunity for a hearing on the record before an administrative law judge.

(2) Any other means authorized by law including but not limited to:

(i) Referral to the Department of Justice for proceedings to enforce any rights of the United States or obligations of the recipient created by the Act or these regulations.

(ii) Use of any requirement of or referral to any Federal, State, or local government agency that will have the effect of correcting a violation of the Act or these regulations.

(b) HHS will limit any termination under § 91.46(a)(1) to the particular recipient and particular program or activity or part of such program and activity HHS finds in violation of these regulations. HHS will not base any part of a termination on a finding with respect to any program or activity of the recipient which does not receive Federal financial assistance from HHS.

(c) HHS will take no action under paragraph (a) until:

(1) The Secretary has advised the recipient of its failure to comply with the Act and these regulations and has determined that voluntary compliance cannot be obtained.

(2) Thirty days have elapsed after the Secretary has sent a written report of the circumstances and grounds of the action to the committees of the Congress having legislative jurisdiction over the Federal program or activity involved. The Secretary will file a report whenever any action is taken under paragraph (a).

(d) HHS also may defer granting new Federal financial assistance from HHS to a recipient when a hearing under § 91.46(a)(1) is initiated.

(1) New Federal financial assistance from HHS includes all assistance for which HHS requires an application or approval, including renewal or continuation of existing activities, or authorization of new activities, during the deferral period. New Federal financial assistance from HHS does not include increases in funding as a result of changed computation of formula awards or assistance approved prior to the beginning of a hearing under § 91.46(a)(1).

(2) HHS will not begin a deferral until the recipient has received a notice of an opportunity for a hearing under § 91.46(a)(1). HHS will not continue a deferral for more than 60 days unless a hearing has begun within that time or the time for beginning the hearing has been extended by mutual consent of the recipient and the Secretary. HHS will not continue a deferral for more than 30 days after the close of the hearing, unless the hearing results in a finding against the recipient.

(3) HHS will limit any deferral to the particular recipient and particular program or activity or part of such program or activity HHS finds in violation of these regulations. HHS will not base any part of a deferral on a finding with respect to any program or activity of the recipient which does

not, and would not in connection with the new funds, receive Federal financial assistance from HHS.

§ 91.47 Hearings, decisions, post-termination proceedings.

Certain HHS procedural provisions applicable to Title VI of the Civil Rights Act of 1964 apply to HHS enforcement of these regulations. They are found at 45 CFR 80.9 through 80.11 and 45 CFR Part 81.

§ 91.48 Remedial action by recipient.

Where HHS finds a recipient has discriminated on the basis of age, the recipient shall take any remedial action that HHS may require to overcome the effects of the discrimination. If another recipient exercises control over the recipient that has discriminated, HHS may require both recipients to take remedial action.

§ 91.49 Alternate funds disbursal procedure.

(a) When HHS withholds funds from a recipient under these regulations, the Secretary may disburse the withheld funds directly to an alternate recipient: any public or non-profit private organization or agency, or State or political subdivision of the State.

(b) The Secretary will require any alternate recipient to demonstrate:

(1) The ability to comply with these regulations; and

(2) The ability to achieve the goals of the Federal statute authorizing the program or activity.

§ 91.50 Exhaustion of administrative remedies.

(a) A complainant may file a civil action following the exhaustion of administrative remedies under the Act. Administrative remedies are exhausted if:

(1) 180 days have elapsed since the complainant filed the complaint and HHS has made no finding with regard to the complaint; or

(2) HHS issues any finding in favor of the recipient.

(b) If HHS fails to make a finding within 180 days or issues a finding in favor of the recipient, HHS shall:

(1) Promptly advise the complainant of this fact; and

(2) Advise the complainant of his or her right to bring a civil action for injunctive relief; and

(3) Inform the complainant:

(i) That the complainant may bring a civil action only in a United States district court for the district in which the recipient is found or transacts business;

(ii) That a complainant prevailing in a civil action has the right to be awarded the costs of the action, including reasonable attorney's fees, but that the complainant must demand these costs in the complaint;

(iii) That before commencing the action the complainant shall give 30 days notice by registered mail to the Secretary, the Attorney General of the United States, and the recipient;

(iv) That the notice must state: the alleged violation of the Act; the relief requested; the court in which the complainant is bringing the action; and, whether or not attorney's fees are demanded in the event the complainant prevails; and

(v) That the complainant may not bring an action if the same alleged violation of the Act by the same recipient is the subject of a pending action in any court of the United States.

PART 92—UNIFORM ADMINISTRATIVE REQUIREMENTS FOR GRANTS AND COOPERATIVE AGREEMENTS TO STATE AND LOCAL GOVERNMENTS

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Subpart A—General

§ 92.1 Purpose and scope of this part.

This part establishes uniform administrative rules for Federal grants and cooperative agreements and subawards to State, local and Indian tribal governments.

§ 92.2 Scope of subpart.

This subpart contains general rules pertaining to this part and procedures for control of exceptions from this part.

§ 92.3 Definitions.

As used in this part:

"Accrued expenditures" mean the charges incurred by the grantee during a given period requiring the provision of funds for: (1) Goods and other tangible property received; (2) services performed by employees, contractors, subgrantees, subcontractors, and other payees; and (3) other amounts becoming owed under programs for which no current services or performance is required, such as annuities, insurance claims, and other benefit payments.

"Accrued income" means the sum of: (1) Earnings during a given period from services performed by the grantee and goods and other tangible property delivered to purchasers, and (2) amounts becoming owed to the grantee for which no current services or performance is required by the grantee.

"Acquisition cost" of an item of purchased equipment means the net invoice unit price of the property including the cost of modifications, attachments, accessories, or auxiliary apparatus necessary to make the property usable for the purpose for which it was acquired. Other charges such as the cost of installation, transportation, taxes, duty or protective in-transit insurance, shall be included or excluded from the unit acquisition cost in accordance with the grantee's regular accounting practices.

"Administrative" requirements mean those matters common to grants in general, such as financial management, kinds and frequency of reports, and retention of records. These are distinguished from *"programmatic"* requirements, which concern matters that can be treated only on a program-by-program or grant-by-grant basis, such as kinds of activities that can be supported by grants under a particular program.

"Awarding agency" means (1) with respect to a grant, the Federal agency, and (2) with respect to a subgrant, the party that awarded the subgrant.

"*Cash contributions*" means the grantee's cash outlay, including the outlay of money contributed to the grantee or subgrantee by other public agencies and institutions, and private organizations and individuals. When authorized by Federal legislation, Federal funds received from other assistance agreements may be considered as grantee or subgrantee cash contributions.

"*Contract*" means (except as used in the definitions for "*grant*" and "*subgrant*" in this section and except where qualified by "*Federal*") a procurement contract under a grant or subgrant, and means a procurement subcontract under a contract.

"*Cost sharing or matching*" means the value of the third party in-kind contributions and the portion of the costs of a federally assisted project or program not borne by the Federal Government.

"*Cost-type contract*" means a contract or subcontract under a grant in which the contractor or subcontractor is paid on the basis of the costs it incurs, with or without a fee.

"*Equipment*" means tangible, nonexpendable, personal property having a useful life of more than one year and an acquisition cost of $5,000 or more per unit. A grantee may use its own definition of equipment provided that such definition would at least include all equipment defined above.

"*Expenditure report*" means: (1) For nonconstruction grants, the SF-269 "Financial Status Report" (or other equivalent report); (2) for construction grants, the SF-271 "Outlay Report and Request for Reimbursement" (or other equivalent report).

"*Federally recognized Indian tribal government*" means the governing body or a governmental agency of any Indian tribe, band, nation, or other organized group or community (including any Native village as defined in section 3 of the Alaska Native Claims Settlement Act, 85 Stat 688) certified by the Secretary of the Interior as eligible for the special programs and services provided by him through the Bureau of Indian Affairs.

"*Government*" means a State or local government or a federally recognized Indian tribal government.

"*Grant*" means an award of financial assistance, including cooperative agreements, in the form of money, or property in lieu of money, by the Federal Government to an eligible grantee. The term does not include technical assistance which provides services instead of money, or other assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct appropriations. Also, the term does not include assistance, such as a fellowship or other lump sum award, which the grantee is not required to account for.

"*Grantee*" means the government to which a grant is awarded and which is accountable for the use of the funds provided. The grantee is the entire legal entity even if only a particular component of the entity is designated in the grant award document.

"*Local government*" means a county, municipality, city, town, township, local public authority (including any public and Indian housing agency under the United States Housing Act of 1937) school district, special district, intrastate district, council of governments (whether or not incorporated as a nonprofit corporation under state law), any other regional or interstate government entity, or any agency or instrumentality of a local government.

"*Obligations*" means the amounts of orders placed, contracts and subgrants awarded, goods and services received, and similar transactions during a given period that will require payment by the grantee during the same or a future period.

"*OMB*" means the United States Office of Management and Budget.

"*Outlays*" (expenditures) mean charges made to the project or program. They may be reported on a cash or accrual basis. For reports prepared on a cash basis, outlays are the sum of actual cash disbursement for direct charges for goods and services, the amount of indirect expense incurred, the value of in-kind contributions applied, and the amount of cash advances and payments made to contractors and subgrantees. For reports prepared on an accrued expenditure basis, outlays are the sum of actual cash disbursements, the amount of indirect expense incurred, the value of inkind contributions applied, and the new increase (or decrease) in the amounts owed by the grantee for goods and other property received, for services performed by employees, contractors, subgrantees, subcontractors, and other payees, and other amounts becoming owed under programs for which no current services or performance are required, such as annuities, insurance claims, and other benefit payments.

"*Percentage of completion method*" refers to a system under which payments are made for construction work according to the percentage of completion of the work, rather than to the grantee's cost incurred.

"*Prior approval*" means documentation evidencing consent prior to incurring specific cost.

"*Real property*" means land, including land improvements, structures and appurtenances thereto, excluding movable machinery and equipment.

"*Share*", when referring to the awarding agency's portion of real property, equipment or supplies, means the same percentage as the awarding agency's portion of the acquiring party's total costs under the grant to which the acquisition costs under the grant to which the acquisition cost of the property was charged. Only costs are to be counted—not the value of third-party in-kind contributions.

"*State*" means any of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State exclusive of local governments. The term does not include any public and Indian housing agency under United States Housing Act of 1937.

"*Subgrant*" means an award of financial assistance in the form of money, or property in lieu of money, made under a grant by a grantee to an eligible subgrantee. The term includes financial assistance when provided by contractual legal agreement, but does not include procurement purchases, nor does it include any form of assistance which is excluded from the definition of "*grant*" in this part.

"*Subgrantee*" means the government or other legal entity to which a subgrant is awarded and which is accountable to the grantee for the use of the funds provided.

"*Supplies*" means all tangible personal property other than "*equipment*" as defined in this part.

"*Suspension*" means depending on the context, either (1) temporary withdrawal of the authority to obligate grant funds pending corrective action by the grantee or subgrantee or a decision to terminate the grant, or (2) an action taken by a suspending official in accordance with agency regulations implementing E.O. 12549 to immediately exclude a person from participating in grant transactions for a period, pending completion of an investigation and such legal or debarment proceedings as may ensue.

"*Termination*" means permanent withdrawal of the authority to obligate previously-awarded grant funds before that authority would otherwise expire. It also means the voluntary relinquishment of that authority by the grantee or subgrantee. "Termination" does not include: (1) Withdrawal of funds awarded on the basis of the grantee's underestimate of the unobligated balance in a prior period; (2) Withdrawal of the unobligated balance as of the expiration of a grant; (3) Refusal to extend a grant or award additional funds, to make a competing or noncompeting continuation, renewal, extension, or supplemental award; or (4) voiding of a grant upon determination that the award was obtained fraudulently, or was otherwise illegal or invalid from inception.

"*Terms of a grant or subgrant*" mean all requirements of the grant or subgrant, whether in statute, regulations, or the award document.

"*Third party in-kind contributions*" mean property or services which benefit a federally assisted project or program and which are contributed by non-Federal third parties without charge to the grantee, or a cost-type contractor under the grant agreement.

"*Unliquidated obligations*" for reports prepared on a cash basis mean the amount of obligations incurred by the grantee that has not been paid. For reports prepared on an accrued expenditure basis, they represent the amount of obligations incurred by the grantee for which an outlay has not been recorded.

"*Unobligated balance*" means the portion of the funds authorized by the Federal agency that has not been obligated by the grantee and is determined by deducting the cumulative obligations from the cumulative funds authorized.

§ 92.4 Applicability.

(a) *General.* Subparts A through D of this part apply to all grants and subgrants to governments, except where inconsistent with Federal statutes or with regulations authorized in accordance with the exception provision of § 92.6, or:

(1) Grants and subgrants to State and local institutions of higher education or State and local hospitals.

(2) The block grants authorized by the Omnibus Budget Reconciliation Act of 1981 (Community Services; Preventive Health and Health Services; Alcohol, Drug Abuse, and Mental Health Services; Maternal and Child Health Services; Social Services; Low-Income Home Energy Assistance; States' Program of Community Development Block Grants for Small Cities; and Elementary and Secondary Education other than programs administered by the Secretary of Education under Title V, Subtitle D, Chapter 2, Section 583—the Secretary's discretionary grant program) and Titles I-III of the Job Training Partnership Act of 1982 and under the Public Health Services Act (Section 1921), Alcohol and Drug Abuse Treatment and Rehabilitation Block Grant and Part C of Title V, Mental Health Service for the Homeless Block Grant).

(3) Entitlement grants to carry out the following programs of the Social Security Act:

(i) Aid to Needy Families with Dependent Children (Title IV-A of the Act, not including the Work Incentive Program (WIN) authorized by section 402(a)19(G); HHS grants for WIN are subject to this part);

(ii) Child Support Enforcement and Establishment of Paternity (Title IV-D of the Act);

(iii) Foster Care and Adoption Assistance (Title IV-E of the Act);

(iv) Aid to the Aged, Blind, and Disabled (Titles I, X, XIV, and XVI-AABD of the Act); and

(v) Medical Assistance (Medicaid) (Title XIX of the Act) not including the State Medicaid Fraud Control program authorized by section 1903(a)(6)(B).

(4) Entitlement grants under the following programs of The National School Lunch Act:

(i) School Lunch (section 4 of the Act),

(ii) Commodity Assistance (section 6 of the Act),

(iii) Special Meal Assistance (section 11 of the Act),

(iv) Summer Food Service for Children (section 13 of the Act), and

(v) Child Care Food Program (section 17 of the Act).

(5) Entitlement grants under the following programs of The Child Nutrition Act of 1966:

(i) Special Milk (section 3 of the Act), and

(ii) School Breakfast (section 4 of the Act).

(6) Entitlement grants for State Administrative expenses under The Food Stamp Act of 1977 (section 16 of the Act).

(7) A grant for an experimental, pilot, or demonstration project that is also supported by a grant listed in paragraph (a)(3) of this section;

(8) Grant funds awarded under subsection 412(e) of the Immigration and Nationality Act (8 U.S.C. 1522(e)) and subsection 501(a) of the Refugee Education Assistance Act of 1980 (Pub. L. 96-422, 94 Stat. 1809), for cash assistance, medical assistance, and supplemental security income benefits to refugees and entrants and the administrative costs of providing the assistance and benefits;

(9) Grants to local education agencies under 20 U.S.C. 236 through 241-1(a), and 242 through 244 (portions of the Impact Aid program), except for 20 U.S.C. 238(d)(2)(c) and 240(f) (Entitlement Increase for Handicapped Children); and

(10) Payments under the Veterans Administration's State Home Per Diem Program (38 U.S.C. 641(a)).

(b) *Entitlement programs.* Entitlement programs enumerated above in

§ 92.4(a) (3) through (8) are subject to Subpart E.

§ 92.5 Effect on other issuances.

All other grants administration provisions of codified program regulations, program manuals, handbooks and other nonregulatory materials which are inconsistent with this part are superseded, except to the extent they are required by statute, or authorized in accordance with the exception provision in § 92.6.

§ 92.6 Additions and exceptions.

(a) For classes of grants and grantees subject to this part, Federal agencies may not impose additional administrative requirements except in codified regulations published in the FEDERAL REGISTER.

(b) Exceptions for classes of grants or grantees may be authorized only by OMB.

(c) Exceptions on a case-by-case basis and for subgrantees may be authorized by the affected Federal agencies.

Subpart B—Pre-Award Requirements

§ 92.10 Forms for applying for grants.

(a) *Scope.* (1) This section prescribes forms and instructions to be used by governmental organizations (except hospitals and institutions of higher education operated by a government) in applying for grants. This section is not applicable, however, to formula grant programs which do not require applicants to apply for funds on a project basis.

(2) This section applies only to applications to Federal agencies for grants, and is not required to be applied by grantees in dealing with applicants for subgrants. However, grantees are encouraged to avoid more detailed or burdensome application requirements for subgrants.

(b) *Authorized forms and instructions for governmental organizations.* (1) In applying for grants, applicants shall only use standard application forms or those prescribed by the granting agency with the approval of OMB under the Paperwork Reduction Act of 1980.

(2) Applicants are not required to submit more than the original and two copies of preapplications or applications.

(3) Applicants must follow all applicable instructions that bear OMB clearance numbers. Federal agencies may specify and describe the programs, functions, or activities that will be used to plan, budget, and evaluate the work under a grant. Other supplementary instructions may be issued only with the approval of OMB to the extent required under the Paperwork Reduction Act of 1980. For any standard form, except the SF-424 facesheet, Federal agencies may shade out or instruct the applicant to disregard any line item that is not needed.

(4) When a grantee applies for additional funding (such as a continuation or supplemental award) or amends a previously submitted application, only the affected pages need be submitted. Previously submitted pages with information that is still current need not be resubmitted.

§ 92.11 State plans.

(a) *Scope.* The statutes for some programs require States to submit plans before receiving grants. Under regulations implementing Executive Order 12372, "Intergovernmental Review of Federal Programs," States are allowed to simplify, consolidate and substitute plans. This section contains additional provisions for plans that are subject to regulations implementing the Executive order.

(b) *Requirements.* A State need meet only Federal administrative or programmatic requirements for a plan that are in statutes or codified regulations.

(c) *Assurances.* In each plan the State will include an assurance that the State shall comply with all applicable Federal statutes and regulations in effect with respect to the periods for which it receives grant funding. For this assurance and other assurances required in the plan, the State may:

(1) Cite by number the statutory or regulatory provisions requiring the assurances and affirm that it gives the

assurances required by those provisions,

(2) Repeat the assurance language in the statutes or regulations, or

(3) Develop its own language to the extent permitted by law.

(d) *Amendments.* A State will amend a plan whenever necessary to reflect: (1) New or revised Federal statutes or regulations or (2) a material change in any State law, organization, policy, or State agency operation. The State will obtain approval for the amendment and its effective date but need submit for approval only the amended portions of the plan.

§ 92.12 Special grant or subgrant conditions for "high-risk" grantees.

(a) A grantee or subgrantee may be considered "high risk" if an awarding agency determines that a grantee or subgrantee:

(1) Has a history of unsatisfactory performance, or

(2) Is not financially stable, or

(3) Has a management system which does not meet the management standards set forth in this part, or

(4) Has not conformed to terms and conditions of previous awards, or

(5) Is otherwise not responsible; and if the awarding agency determines that an award will be made, special conditions and/or restrictions shall correspond to the high risk condition and shall be included in the award.

(b) Special conditions or restrictions may include:

(1) Payment on a reimbursement basis;

(2) Withholding authority to proceed to the next phase until receipt of evidence of acceptable performance within a given funding period;

(3) Requiring additional, more detailed financial reports;

(4) Additional project monitoring;

(5) Requiring the grante or subgrantee to obtain technical or management assistance; or

(6) Establishing additional prior approvals.

(c) If an awarding agency decides to impose such conditions, the awarding official will notify the grantee or subgrantee as early as possible, in writing, of:

(1) The nature of the special conditions/restrictions;

(2) The reason(s) for imposing them;

(3) The corrective actions which must be taken before they will be removed and the time allowed for completing the corrective actions and

(4) The method of requesting reconsideration of the conditions/restrictions imposed.

Subpart C—Post-Award Requirements

FINANCIAL ADMINISTRATION

§ 92.20 Standards for financial management systems.

(a) A State must expand and account for grant funds in accordance with State laws and procedures for expending and accounting for its own funds. Fiscal control and accounting procedures of the State, as well as its subgrantees and cost-type contractors, must be sufficient to—

(1) Permit preparation of reports required by this part and the statutes authorizing the grant, and

(2) Permit the tracing of funds to a level of expenditures adequate to establish that such funds have not been used in violation of the restrictions and prohibitions of applicable statutes.

(b) The financial management systems of other grantees and subgrantees must meet the following standards:

(1) *Financial reporting.* Accurate, current, and complete disclosure of the financial results of financially assisted activities must be made in accordance with the financial reporting requirements of the grant or subgrant.

(2) *Accounting records.* Grantees and subgrantees must maintain records which adequately identify the source and application of funds provided for financially-assisted activities. These records must contain information pertaining to grant or subgrant awards and authorizations, obligations, unobligated balances, assets, liabilities, outlays or expenditures, and income.

(3) *Internal control.* Effective control and accountability must be maintained for all grant and subgrant cash,

real and personal property, and other assets. Grantees and subgrantees must adequately safeguard all such property and must assure that it is used solely for authorized purposes.

(4) *Budget control.* Actual expenditures or outlays must be compared with budgeted amounts for each grant or subgrant. Financial information must be related to performance or productivity data, including the development of unit cost information whenever appropriate or specifically required in the grant or subgrant agreement. If unit cost data are required, estimates based on available documentation will be accepted whenever possible.

(5) *Allowable cost.* Applicable OMB cost principles, agency program regulations, and the terms of grant and subgrant agreements will be followed in determining the reasonableness, allowability, and allocability of costs.

(6) *Source documentation.* Accounting records must be supported by such source documentation as cancelled checks, paid bills, payrolls, time and attendance records, contract and subgrant award documents, etc.

(7) *Cash management.* Procedures for minimizing the time elapsing between the transfer of funds from the U.S. Treasury and disbursement by grantees and subgrantees must be followed whenever advance payment procedures are used. Grantees must establish reasonable procedures to ensure the receipt of reports on subgrantees' cash balances and cash disbursements in sufficient time to enable them to prepare complete and accurate cash transactions reports to the awarding agency. When advances are made by letter-of-credit or electronic transfer of funds methods, the grantee must make drawdowns as close as possible to the time of making disbursements. Grantees must monitor cash drawdowns by their subgrantees to assure that they conform substantially to the same standards of timing and amount as apply to advances to the grantees.

(c) An awarding agency may review the adequacy of the financial management system of any applicant for financial assistance as part of a preaward review or at any time subsequent to award.

§ 92.21 Payment.

(a) *Scope.* This section prescribes the basic standard and the methods under which a Federal agency will make payments to grantees, and grantees will make payments to subgrantees and contractors.

(b) *Basic standard.* Methods and procedures for payment shall minimize the time elapsing between the transfer of funds and disbursement by the grantee or subgrantee, in accordance with Treasury regulations at 31 CFR Part 205.

(c) *Advances.* Grantees and subgrantees shall be paid in advance, provided they maintain or demonstrate the willingness and ability to maintain procedures to minimize the time elapsing between the transfer of the funds and their disbursement by the grantee or subgrantee.

(d) *Reimbursement.* Reimbursement shall be the preferred method when the requirements in paragraph (c) of this section are not met. Grantees and subgrantees may also be paid by reimbursement for any construction grant. Except as otherwise specified in regulation, Federal agencies shall not use the percentage of completion method to pay construction grants. The grantee or subgrantee may use that method to pay its construction contractor, and if it does, the awarding agency's payments to the grantee or subgrantee will be based on the grantee's or subgrantee's actual rate of disbursement.

(e) *Working capital advances.* If a grantee cannot meet the criteria for advance payments described in paragraph (c) of this section, and the Federal agency has determined that reimbursement is not feasible because the grantee lacks sufficient working capital, the awarding agency may provide cash or a working capital advance basis. Under this procedure the awarding agency shall advance cash to the grantee to cover its estimated disbursement needs for an initial period generally geared to the grantee's disbursing cycle. Thereafter, the awarding agency shall reimburse the grantee for its actual cash disbursements. The working capital advance method of payment shall not be used by grantees or subgrantees if the reason for using such method is the unwillingness or inability of the grantee to provide timely advances to the subgrantee to meet the subgrantee's actual cash disbursements.

(f) *Effect of program income, refunds, and audit recoveries on payment.* (1) Grantees and subgrantees shall disburse repayments to and interest earned on a revolving fund before requesting additional cash payments for the same activity.

(2) Except as provided in paragraph (f)(1) of this section, grantees and subgrantees shall disburse program income, rebates, refunds, contract settlements, audit recoveries and interest earned on such funds before requesting additional cash payments.

(g) *Withholding payments.* (1) Unless otherwise required by Federal statute, awarding agencies shall not withhold payments for proper charges incurred by grantees or subgrantees unless—

(i) The grantee or subgrantee has failed to comply with grant award conditions or

(ii) The grantee or subgrantee is indebted to the United States.

(2) Cash withheld for failure to comply with grant award condition, but without suspension of the grant, shall be released to the grantee upon subsequent compliance. When a grant is suspended, payment adjustments will be made in accordance with § 92.43(c).

(3) A Federal agency shall not make payment to grantees for amounts that are withheld by grantees or subgrantees from payment to contractors to assure satisfactory completion of work. Payments shall be made by the Federal agency when the grantees or subgrantees actually disburse the withheld funds to the contractors or to escrow accounts established to assure satisfactory completion of work.

(h) *Cash depositories.* (1) Consistent with the national goal of expanding the opportunities for minority business enterprises, grantees and subgrantees are encouraged to use minority banks (a bank which is owned at least 50 percent by minority group members). A list of minority owned banks can be obtained from the Minority Business Development Agency, Department of Commerce, Washington, DC 20230.

(2) A grantee or subgrantee shall maintain a separate bank account only when required by Federal-State agreement.

(i) *Interest earned on advances.* Except for interest earned on advances of funds exempt under the Intergovernmental Cooperation Act (31 U.S.C. 6501 et seq.) and the Indian Self-Determination Act (23 U.S.C. 450), grantees and subgrantees shall promptly, but at least quarterly, remit interest earned on advances to the Federal agency. The grantee or subgrantee may keep interest amounts up to $100 per year for administrative expenses.

§ 92.22 Allowable costs.

(a) *Limitation on use of funds.* Grant funds may be used only for:

(1) The allowable costs of the grantees, subgrantees and cost-type contractors, including allowable costs in the form of payments to fixed-price contractors; and

(2) Reasonable fees or profit to cost-type contractors but not any fee or profit (or other increment above allowable costs) to the grantee or subgrantee.

(b) *Applicable cost principles.* For each kind of organization, there is a set of Federal principles for determining allowable costs. Allowable costs will be determined in accordance with the cost principles applicable to the organization incurring the costs. The following chart lists the kinds of organizations and the applicable cost principles.

For the costs of a—	Use the principles in—
State, local or Indian tribal government.	OMB Circular A-87.
Private nonprofit organization other than an (1) institution of higher education, (2) hospital, or (3) organization named in OMB Circular A-122 as not subject to that circular.	OMB Circular A-122.
Educational institutions	OMB Circular A-21.

For the costs of a—	Use the principles in—
For-profit organization other than a hospital and an organization named in OBM Circular A-122 as not subject to that circular.	48 CFR Part 31. Contract Cost Principles and Procedures, or uniform cost accounting standards that comply with cost principles acceptable to the Federal agency.

§ 92.23 Period of availability of funds.

(a) *General.* Where a funding period is specified, a grantee may charge to the award only costs resulting from obligations of the funding period unless carryover of unobligated balances is permitted, in which case the carryover balances may be charged for costs resulting from obligations of the subsequent funding period.

(b) *Liquidation of obligations.* A grantee must liquidate all obligations incurred under the award not later than 90 days after the end of the funding period (or as specified in a program regulation) to coincide with the submission of the annual Financial Status Report (SF-269). The Federal agency may extend this deadline at the request of the grantee.

§ 92.24 Matching or cost sharing.

(a) *Basic rule: Costs and contributions acceptable.* With the qualifications and exceptions listed in paragraph (b) of this section, a matching or cost sharing requirement may be satisfied by either or both of the following:

(1) Allowable costs incurred by the grantee, subgrantee or a cost-type contractor under the assistance agreement. This includes allowable costs borne by non-Federal grants or by others cash donations from non-Federal third parties.

(2) The value of third party in-kind contributions applicable to the period to which the cost sharing or matching requirements applies.

(b) *Qualifications and exceptions*—(1) *Costs borne by other Federal grant agreements.* Except as provided by Federal statute, a cost sharing or matching requirement may not be met by costs borne by another Federal grant. This prohibition does not apply to income earned by a grantee or subgrantee from a contract awarded under another Federal grant.

(2) *General revenue sharing.* For the purpose of this section, general revenue sharing funds distributed under 31 U.S.C. 6702 are not considered Federal grant funds.

(3) *Cost or contributions counted towards other Federal costs-sharing requirements.* Neither costs nor the values of third party in-kind contributions may count towards satisfying a cost sharing or matching requirement of a grant agreement if they have been or will be counted towards satisfying a cost sharing or matching requirement of another Federal grant agreement, a Federal procurement contract, or any other award of Federal funds.

(4) *Costs financed by program income.* Costs financed by program income, as defined in § 92.25, shall not count towards satisfying a cost sharing or matching requirement unless they are expressly permitted in the terms of the assistance agreement. (This use of general program income is described in § 92.25(g).)

(5) *Services or property financed by income earned by contractors.* Contractors under a grant may earn income from the activities carried out under the contract in addition to the amounts earned from the party awarding the contract. No costs of services or property supported by this income may count toward satisfying a cost sharing or matching requirement unless other provisions of the grant agreement expressly permit this kind of income to be used to meet the requirement.

(6) *Records.* Costs and third party in-kind contributions counting towards satisfying a cost sharing or matching requirement must be verifiable from the records of grantees and subgrantee or cost-type contractors. These records must show how the value placed on third party in-kind contributions was derived. To the extent feasible, volunteer services will be supported by the same methods that the organization uses to support the allocability of regular personnel costs.

(7) *Special standards for third party in-kind contributions.* (i) Third party in-kind contributions count towards

satisfying a cost sharing or matching requirement only where, if the party receiving the contributions were to pay for them, the payments would be allowable costs.

(ii) Some third party in-kind contributions are goods and services that, if the grantee, subgrantee, or contractor receiving the contribution had to pay for them, the payments would have been an indirect costs. Costs sharing or matching credit for such contributions shall be given only if the grantee, subgrantee, or contractor has established, along with its regular indirect cost rate, a special rate for allocating to individual projects or programs the value of the contributions.

(iii) A third party in-kind contribution to a fixed-price contract may count towards satisfying a cost sharing or matching requirement only if it results in:

(A) An increase in the services or property provided under the contract (without additional cost to the grantee or subgrantee) or

(B) A cost savings to the grantee or subgrantee.

(iv) The values placed on third party in-kind contributions for cost sharing or matching purposes will conform to the rules in the succeeding sections of this part. If a third party in-kind contribution is a type not treated in those sections, the value placed upon it shall be fair and reasonable.

(c) *Valuation of donated services*—(1) *Volunteer services.* Unpaid services provided to a grantee or subgrantee by individuals will be valued at rates consistent with those ordinarily paid for similar work in the grantee's or subgrantee's organization. If the grantee or subgrantee does not have employees performing similar work, the rates will be consistent with those ordinarily paid by other employers for similar work in the same labor market. In either case, a reasonable amount for fringe benefits may be included in the valuation.

(2) *Employees of other organizations.* When an employer other than a grantee, subgrantee, or cost-type contractor furnishes free of charge the services of an employee in the employee's normal line of work, the services will be valued at the employee's regular rate of pay exclusive of the employee's fringe benefits and overhead costs. If the services are in a different line of work, paragraph (c)(1) of this section applies.

(d) *Valuation of third party donated supplies and loaned equipment or space.* (1) If a third party donates supplies, the contribution will be valued at the market value of the supplies at the time of donation.

(2) If a third party donates the use of equipment or space in a building but retains title, the contribution will be valued at the fair rental rate of the equipment or space.

(e) *Valuation of third party donated equipment, buildings, and land.* If a third party donates equipment, buildings, or land, and title passes to a grantee or subgrantee, the treatment of the donated property will depend upon the purpose of the grant or subgrant, as follows:

(1) *Awards for capital expenditures.* If the purpose of the grant or subgrant is to assist the grantee or subgrantee in the acquisition of property, the market value of that property at the time of donation may be counted as cost sharing or matching,

(2) *Other awards.* If assisting in the acquisition of property is not the purpose of the grant or subgrant, paragraphs (e)(2) (i) and (ii) of this section apply:

(i) If approval is obtained from the awarding agency, the market value at the time of donation of the donated equipment or buildings and the fair rental rate of the donated land may be counted as cost sharing or matching. In the case of a subgrant, the terms of the grant agreement may require that the approval be obtained from the Federal agency as well as the grantee. In all cases, the approval may be given only if a purchase of the equipment or rental of the land would be approved as an allowable direct cost. If any part of the donated property was acquired with Federal funds, only the non-federal share of the property may be counted as cost-sharing or matching.

(ii) If approval is not obtained under paragraph (e)(2)(i) of this section, no amount may be counted for donated land, and only depreciation or use allowances may be counted for donated equipment and buildings. The depreciation or use allowances for this property are not treated as third party in-kind contributions. Instead, they are treated as costs incurred by the grantee or subgrantee. They are computed and allocated (usually as indirect costs) in accordance with the cost principles specified in § 92.22, in the same way as depreciation or use allowances for purchased equipment and buildings. The amount of depreciation or use allowances for donated equipment and buildings is based on the property's market value at the time it was donated.

(f) *Valuation of grantee or subgrantee donated real property for construction/acquisition.* If a grantee or subgrantee donates real property for a construction or facilities acquisition project, the current market value of that property may be counted as cost sharing or matching. If any part of the donated property was acquired with Federal funds, only the non-federal share of the property may be counted as cost sharing or matching.

(g) *Appraisal of real property.* In some cases under paragraphs (d), (e) and (f) of this section, it will be necessary to establish the market value of land or a building or the fair rental rate of land or of space in a building. In these cases, the Federal agency may require the market value or fair rental value be set by an independent appraiser, and that the value or rate be certified by the grantee. This requirement will also be imposed by the grantee on subgrantees.

§ 92.25 Program income.

(a) *General.* Grantees are encouraged to earn income to defray program costs. Program income includes income from fees for services performed, from the use or rental of real or personal property acquired with grant funds, from the sale of commodities or items fabricated under a grant agreement, and from payments of principal and interest on loans made with grant funds. Except as otherwise provided in regulations of the Federal agency, program income does not include interest on grant funds, rebates, credits, discounts, refunds, etc. and interest earned on any of them.

(b) *Definition of program income.* Program income means gross income received by the grantee or subgrantee directly generated by a grant supported activity, or earned only as a result of the grant agreement during the grant period. "During the grant period" is the time between the effective date of the award and the ending date of the award reflected in the final financial report.

(c) *Cost of generating program income.* If authorized by Federal regulations or the grant agreement, costs incident to the generation of program income may be deducted from gross income to determine program income.

(d) *Governmental revenues.* Taxes, special assessments, levies, fines, and other such revenues raised by a grantee or subgrantee are not program income unless the revenues are specifically identified in the grant agreement or Federal agency regulations as program income.

(e) *Royalties.* Income from royalties and license fees for copyrighted material, patents, and inventions developed by a grantee or subgrantee is program income only if the revenues are specifically identified in the grant agreement or Federal agency regulations as program income. (See § 92.34.)

(f) *Property.* Proceeds from the sale of real property or equipment will be handled in accordance with the requirements of §§ 92.31 and 92.32.

(g) *Use of program income.* Program income shall be deducted from outlays which may be both Federal and non-Federal as described below, unless the Federal agency regulations or the grant agreement specify another alternative (or a combination of the alternatives). In specifying alternatives, the Federal agency may distinguish between income earned by the grantee and income earned by subgrantees and between the sources, kinds, or amounts of income. When Federal agencies authorize the alternatives in paragraphs (g) (2) and (3) of this section, program income in excess of any limits stipulated shall also be deducted from outlays.

(1) *Deduction.* Ordinarily program income shall be deducted from total allowable costs to determine the net allowable costs. Program income shall

be used for current costs unless the Federal agency authorizes otherwise. Program income which the grantee did not anticipate at the time of the award shall be used to reduce the Federal agency and grantee contributions rather than to increase the funds committed to the project.

(2) *Addition.* When authorized, program income may be added to the funds committed to the grant agreement by the Federal agency and the grantee. The program income shall be used for the purposes and under the conditions of the grant agreement.

(3) *Cost sharing or matching.* When authorized, program income may be used to meet the cost sharing or matching requirement of the grant agreement. The amount of the Federal grant award remains the same.

(h) *Income after the award period.* There are no Federal requirements governing the disposition of program income earned after the end of the award period (i.e., until the ending date of the final financial report, see paragraph (a) of this section), unless the terms of the agreement or the Federal agency regulations provide otherwise.

§ 92.26 Non-Federal audit.

(a) *Basic rule.* Grantees and subgrantees are responsible for obtaining audits in accordance with the Single Audit Act of 1984 (31 U.S.C. 7501-7) and Federal agency implementing regulations. The audits shall be made by an independent auditor in accordance with generally accepted government auditing standards covering financial and compliance audits.

(b) *Subgrantees.* State or local governments, as those terms are defined for purposes of the Single Audit Act, that receive Federal financial assistance and provide $25,000 or more of it in a fiscal year to a subgrantee shall:

(1) Determine whether State or local subgrantees have met the audit requirements of the Act and whether subgrantees covered by OMB Circular A-110, "Uniform Requirements for Grants and Other Agreements with Institutions of Higher Education, Hospitals and Other Nonprofit Organizations" have met the audit requirement. Commercial contractors (private forprofit and private and governmental organizations) providing goods and services to State and local governments are not required to have a single audit performed. State and local govenments should use their own procedures to ensure that the contractor has complied with laws and regulations affecting the expenditure of Federal funds;

(2) Determine whether the subgrantee spent Federal assistance funds provided in accordance with applicable laws and regulations. This may be accomplished by reviewing an audit of the subgrantee made in accordance with the Act, Circular A-110, or through other means (e.g., program reviews) if the subgrantee has not had such an audit;

(3) Ensure that appropriate corrective action is taken within six months after receipt of the audit report in instance of noncompliance with Federal laws and regulations;

(4) Consider whether subgrantee audits necessitate adjustment of the grantee's own records; and

(5) Require each subgrantee to permit independent auditors to have access to the records and financial statements.

(c) *Auditor selection.* In arranging for audit services, § 92.36 shall be followed.

CHANGES, PROPERTY, AND SUBAWARDS

§ 92.30 Changes.

(a) *General.* Grantees and subgrantees are permitted to rebudget within the approved direct cost budget to meet unanticipated requirements and may make limited program changes to the approved project. However, unless waived by the awarding agency, certain types of post-award changes in budgets and projects shall require the prior written approval of the awarding agency.

(1) Approvals shall not be valid unless they are in writing, and signed by at least one of the following officials of the Department of Health and Human Services (HHS):

(i) The responsible Grants Officer or his or her designee;

(ii) The head of the HHS Operating or Staff Division that awarded the grant; or

(iii) The head of the Regional Office of the HHS Operating or Staff Division that awarded the grant.

(b) *Relation to cost principles.* The applicable cost principles (see § 92.22) contain requirements for prior approval of certain types of costs. Except where waived, those requirements apply to all grants and subgrants even if paragraphs (c) through (f) of this section do not.

(c) *Budget changes*—(1) *Nonconstruction projects.* Except as stated in other regulations or an award document, grantees or subgrantees shall obtain the prior approval of the awarding agency whenever any of the following changes is anticipated under a nonconstruction award:

(i) Any revision which would result in the need for additional funding.

(ii) Unless waived by the awarding agency, cumulative transfers among direct cost categories, or, if applicable, among separately budgeted programs, projects, functions, or activities which exceed or are expected to exceed ten percent of the current total approved budget, whenever the awarding agency's share exceeds $100,000.

(iii) Transfer of funds allotted for training allowances (i.e., from direct payments to trainees to other expense categories).

(2) *Construction projects.* Grantees and subgrantees shall obtain prior written approval for any budget revision which would result in the need for additional funds.

(3) *Combined construction and nonconstruction projects.* When a grant or subgrant provides funding for both construction and nonconstruction activities, the grantee or subgrantee must obtain prior written approval from the awarding agency before making any fund or budget transfer from nonconstruction to construction or vice versa.

(d) *Programmatic changes.* Grantees or subgrantees must obtain the prior approval of the awarding agency whenever any of the following actions is anticipated:

(1) Any revision of the scope or objectives of the project (regardless of whether there is an associated budget revision requiring prior approval).

(2) Need to extend the period of availability of funds.

(3) Changes in key persons in cases where specified in an application or a grant award. In research projects, a change in the project director or principal investigator shall always require approval unless waived by the awarding agency.

(4) Under nonconstruction projects, contracting out, subgranting (if authorized by law) or otherwise obtaining the services of a third party to perform activities which are central to the purposes of the award. This approval requirement is in addition to the approval requirements of § 92.36 but does not apply to the procurement of equipment, supplies, and general support services.

(5) Providing medical care to individuals under research grants.

(e) *Additional prior approval requirements.* The awarding agency may not require prior approval for any budget revision which is not described in paragraph (c) of this section.

(f) *Requesting prior approval.* (1) A request for prior approval of any budget revision will be in the same budget formal the grantee used in its application and shall be accompanied by a narrative justification for the proposed revision.

(2) A request for a prior approval under the applicable Federal cost principles (see § 92.22) may be made by letter.

(3) A request by a subgrantee for prior approval will be addressed in writing to the grantee. The grantee will promptly review such request and shall approve or disapprove the request in writing. A grantee will not approve any budget or project revision which is inconsistent with the purpose or terms and conditions of the Federal grant to the grantee. If the revision, requested by the subgrantee would result in a change to the grantee's approved project which requires Federal prior approval, the grantee will obtain the Federal agency's approval before approving the subgrantee's request.

[53 FR 8079, 8087, Mar. 11, 1988, as amended at 53 FR 8079, Mar. 11, 1988]

§ 92.31 Real property.

(a) *Title.* Subject to the obligations and conditions set forth in this section, title to real property acquired under a grant or subgrant will vest upon acquisition in the grantee or subgrantee respectively.

(b) *Use.* Except as otherwise provided by Federal statutes, real property will be used for the originally authorized purposes as long as needed for that purposes, and the grantee or subgrantee shall not dispose of or encumber its title or other interests.

(c) *Disposition.* When real property is no longer needed for the originally authorized purpose, the grantee or subgrantee will request disposition instructions from the awarding agency. The instructions will provide for one of the following alternatives:

(1) *Retention of title.* Retain title after compensating the awarding agency. The amount paid to the awarding agency will be computed by applying the awarding agency's percentage of participation in the cost of the original purchase to the fair market value of the property. However, in those situations where a grantee or subgrantee is disposing of real property acquired with grant funds and acquiring replacement real property under the same program, the net proceeds from the disposition may be used as an offset to the cost of the replacement property.

(2) *Sale of property.* Sell the property and compensate the awarding agency. The amount due to the awarding agency will be calculated by applying the awarding agency's percentage of participation in the cost of the original purchase to the proceeds of the sale after deduction of any actual and reasonable selling and fixing-up expenses. If the grant is still active, the net proceeds from sale may be offset against the original cost of the property. When a grantee or subgrantee is directed to sell property, sales procedures shall be followed that provide for competition to the extent practicable and result in the highest possible return.

(3) *Transfer of title.* Transfer title to the awarding agency or to a third-party designated/approved by the awarding agency. The grantee or subgrantee shall be paid an amount calculated by applying the grantee or subgrantee's percentage of participation in the purchase of the real property to the current fair market value of the property.

§ 92.32 Equipment.

(a) *Title.* Subject to the obligations and conditions set forth in this section, title to equipment acquired under a grant or subgrant will vest upon acquisition in the grantee or subgrantee respectively.

(b) *States.* A State will use, manage, and dispose of equipment acquired under a grant by the State in accordance with State laws and procedures. Other grantees and subgrantees will follow paragraphs (c) through (e) of this section.

(c) *Use.* (1) Equipment shall be used by the grantee or subgrantee in the program or project for which it was acquired as long as needed, whether or not the project or program continues to be supported by Federal funds. When no longer needed for the original program or project, the equipment may be used in other activities currently or previously supported by a Federal agency.

(2) The grantee or subgrantee shall also make equipment available for use on other projects or programs currently or previously supported by the Federal Government, providing such use will not interfere with the work on the projects or program for which it was originally acquired. First preference for other use shall be given to other programs or projects supported by the awarding agency. User fees should be considered if appropriate.

(3) Notwithstanding the encouragement in § 92.25(a) to earn program income, the grantee or subgrantee must not use equipment acquired with grant funds to provide services for a fee to compete unfairly with private companies that provide equivalent services, unless specifically permitted or contemplated by Federal statute.

(4) When acquiring replacement equipment, the grantee or subgrantee may use the equipment to be replaced as a trade-in or sell the property and use the proceeds to offset the cost of

the replacement property, subject to the approval of the awarding agency.

(d) *Management requirements.* Procedures for managing equipment (including replacement equipment), whether acquired in whole or in part with grant funds, until disposition takes place will, as a minimum, meet the following requirements:

(1) Property records must be maintained that include a description of the property, a serial number or other identification number, the source of property, who holds title, the acquisition date, and cost of the property, percentage of Federal participation in the cost of the property, the location, use and condition of the property, and any ultimate disposition data including the date of disposal and sale price of the property.

(2) A physical inventory of the property must be taken and the results reconciled with the property records at least once every two years.

(3) A control system must be developed to ensure adequate safeguards to prevent loss, damage, or theft of the property. Any loss, damage, or theft shall be investigated.

(4) Adequate maintenance procedures must be developed to keep the property in good condition.

(5) If the grantee or subgrantee is authorized or required to sell the property, proper sales procedures must be established to ensure the highest possible return.

(e) *Disposition.* When original or replacement equipment acquired under a grant or subgrant is no longer needed for the original project or program or for other activities currently or previously supported by a Federal agency, disposition of the equipment will be made as follows:

(1) Items of equipment with a current per-unit fair market value of less than $5,000 may be retained, sold or otherwise disposed of with no further obligation to the awarding agency.

(2) Items of equipment with a current per unit fair market value in excess of $5,000 may be retained or sold and the awarding agency shall have a right to an amount calculated by multiplying the current market value or proceeds from sale by the awarding agency's share of the equipment.

(3) In cases where a grantee or subgrantee fails to take appropriate disposition actions, the awarding agency may direct the grantee or subgrantee to take excess and disposition actions.

(f) *Federal equipment.* In the event a grantee or subgrantee is provided federally-owned equipment:

(1) Title will remain vested in the Federal Government.

(2) Grantees or subgrantees will manage the equipment in accordance with Federal agency rules and procedures, and submit an annual inventory listing.

(3) When the equipment is no longer needed, the grantee or subgrantee will request disposition instructions from the Federal agency.

(g) *Right to transfer title.* The Federal awarding agency may reserve the right to transfer title to the Federal Government or a third part named by the awarding agency when such a third party is otherwise eligible under existing statutes. Such transfers shall be subject to the following standards:

(1) The property shall be identified in the grant or otherwise made known to the grantee in writing.

(2) The Federal awarding agency shall issue disposition instruction within 120 calendar days after the end of the Federal support of the project for which it was acquired. If the Federal awarding agency fails to issue disposition instructions within the 120 calendar-day period the grantee shall follow § 92.32(e).

(3) When title to equipment is transferred, the grantee shall be paid an amount calculated by applying the percentage of participation in the purchase to the current fair market value of the property.

§ 92.33 Supplies.

(a) *Title.* Title to supplies acquired under a grant or subgrant will vest, upon acquisition, in the grantee or subgrantee respectively.

(b) *Disposition.* If there is a residual inventory of unused supplies exceeding $5,000 in total aggregate fair market value upon termination or completion of the award, and if the supplies are not needed for any other federally sponsored programs or projects, the grantee or subgrantee shall compensate the awarding agency for its share.

§ 92.34 Copyrights.

The Federal awarding agency reserves a royalty-free, nonexclusive, and irrevocable license to reproduce, publish or otherwise use, and to authorize others to use, for Federal Government purposes:

(a) The copyright in any work developed under a grant, subgrant, or contract under a grant or subgrant; and

(b) Any rights of copyright to which a grantee, subgrantee or a contractor purchases ownership with grant support.

§ 92.35 Subawards to debarred and suspended parties.

Grantees and subgrantees must not make any award or permit any award (subgrant or contract) at any tier to any party which is debarred or suspended or is otherwise excluded from or ineligible for participation in Federal assistance programs under Executive Order 12549, "Debarment and Suspension."

§ 92.36 Procurement.

(a) *States.* When procuring property and services under a grant, a State will follow the same policies and procedures it uses for procurements from its non-Federal funds. The State will ensure that every purchase order or other contract includes any clauses required by Federal statutes and executive orders and their implementing regulations. Other grantees and subgrantees will follow paragraphs (b) through (i) in this section.

(b) *Procurement standards.* (1) Grantees and subgrantees will use their own procurement procedures which reflect applicable State and local laws and regulations, provided that the procurements conform to applicable Federal law and the standards identified in this section.

(2) Grantees and subgrantees will maintain a contract administration system which ensures that contractors perform in accordance with the terms, conditions, and specifications of their contracts or purchase orders.

(3) Grantees and subgrantees will maintain a written code of standards of conduct governing the performance of their employees engaged in the award and administration of contracts. No employee, officer or agent of the grantee or subgrantee shall participate in selection, or in the award or administration of a contract supported by Federal funds if a conflict of interest, real or apparent, would be involved. Such a conflict would arise when:

(i) The employee, officer or agent,

(ii) Any member of his immediate family,

(iii) His or her partner, or

(iv) An organization which employs, or is about to employ, any of the above, has a financial or other interest in the firm selected for award. The grantee's or subgrantee's officers, employees or agents will neither solicit nor accept gratuities, favors or anything of monetary value from contractors, potential contractors, or parties to subagreements. Grantee and subgrantees may set minimum rules where the financial interest is not substantial or the gift is an unsolicited item of nominal intrinsic value. To the extent permitted by State or local law or regulations, such standards or conduct will provide for penalties, sanctions, or other disciplinary actions for violations of such standards by the grantee's and subgrantee's officers, employees, or agents, or by contractors or their agents. The awarding agency may in regulation provide additional prohibitions relative to real, apparent, or potential conflicts of interest.

(4) Grantee and subgrantee procedures will provide for a review of proposed procurements to avoid purchase of unnecessary or duplicative items. Consideration should be given to consolidating or breaking out procurements to obtain a more economical purchase. Where appropriate, an analysis will be made of lease versus purchase alternatives, and any other appropriate analysis to determine the most economical approach.

(5) To foster greater economy and efficiency, grantees and subgrantees are encouraged to enter into State and

local intergovernmental agreements for procurement or use of common goods and services.

(6) Grantees and subgrantees are encouraged to use Federal excess and surplus property in lieu of purchasing new equipment and property whenever such use is feasible and reduces project costs.

(7) Grantees and subgrantees are encouraged to use value engineering clauses in contracts for construction projects of sufficient size to offer reasonable opportunities for cost reductions. Value engineering is a systematic and creative anaylsis of each contract item or task to ensure that its essential function is provided at the overall lower cost.

(8) Grantees and subgrantees will make awards only to responsible contractors possessing the ability to perform successfully under the terms and conditions of a proposed procurement. Consideration will be given to such matters as contractor integrity, compliance with public policy, record of past performance, and financial and technical resources.

(9) Grantees and subgrantees will maintain records sufficient to detail the significant history of a procurement. These records will include, but are not necessarily limited to the following: rationale for the method of procurement, selection of contract type, contractor selection or rejection, and the basis for the contract price.

(10) Grantees and subgrantees will use time and material type contracts only—

(i) After a determination that no other contract is suitable, and

(ii) If the contract includes a ceiling price that the contractor exceeds at its own risk.

(11) Grantees and subgrantees alone will be responsible, in accordance with good administrative practice and sound business judgment, for the settlement of all contractual and administrative issues arising out of procurements. These issues include, but are not limited to source evaluation, protests, disputes, and claims. These standards do not relieve the grantee or subgrantee of any contractual responsibilities under its contracts. Federal agencies will not substitute their judgment for that of the grantee or subgrantee unless the matter is primarily a Federal concern. Violations of law will be referred to the local, State, or Federal authority having proper jurisdiction.

(12) Grantees and subgrantees will have protest procedures to handle and resolve disputes relating to their procurements and shall in all instances disclose information regarding the protest to the awarding agency. A protestor must exhaust all administrative remedies with the grantee and subgrantee before pursuing a protest with the Federal agency. Reviews of protests by the Federal agency will be limited to:

(i) Violations of Federal law or regulations and the standards of this section (violations of State or local law will be under the jurisdiction of State or local authorities) and

(ii) Violations of the grantee's or subgrantee's protest procedures for failure to review a complaint or protest. Protests received by the Federal agency other than those specified above will be referred to the grantee or subgrantee.

(c) *Competition.* (1) All procurement transactions will be conducted in a manner providing full and open competition consistent with the standards of § 92.36. Some of the situations considered to be restrictive of competition include but are not limited to:

(i) Placing unreasonable requirements on firms in order for them to qualify to do business,

(ii) Requiring unnecessary experience and excessive bonding,

(iii) Noncompetitive pricing practices between firms or between affiliated companies,

(iv) Noncompetitive awards to consultants that are on retainer contracts,

(v) Organizational conflicts of interest,

(vi) Specifying only a "brand name" product instead of allowing "an equal" product to be offered and describing the performance of other relevant requirements of the procurement, and

(vii) Any arbitrary action in the procurement process.

(2) Grantees and subgrantees will conduct procurements in a manner that prohibits the use of statutorily or

administratively imposed in-State or local geographical preferences in the evaluation of bids or proposals, except in those cases where applicable Federal statutes expressly mandate or encourage geographic preference. Nothing in this section preempts State licensing laws. When contracting for architectural and engineering (A/E) services, geographic location may be a selection criteria provided its application leaves an appropriate number of qualified firms, given the nature and size of the project, to compete for the contract.

(3) Grantees will have written selection procedures for procurement transactions. These procedures will ensure that all solicitations:

(i) Incorporate a clear and accurate description of the technical requirements for the material, product, or service to be procured. Such description shall not, in competitive procurements, contain features which unduly restrict competition. The description may include a statement of the qualitative nature of the material, product or service to be procured, and when necessary, shall set forth those minimum essential characteristics and standards to which it must conform if it is to satisfy its intended use. Detailed product specifications should be avoided if at all possible. When it is impractical or uneconomical to make a clear and accurate description of the technical requirements, a "brand name or equal" description may be used as a means to define the performance or other salient requirements of a procurement. The specific features of the named brand which must be met by offerors shall be clearly stated; and

(ii) Identify all requirements which the offerors must fulfill and all other factors to be used in evaluating bids or proposals.

(4) Grantees and subgrantees will ensure that all prequalified lists of persons, firms, or products which are used in acquiring goods and services are current and include enough qualified sources to ensure maximum open and free competition. Also, grantees and subgrantees will not preclude potential bidders from qualifying during the solicitation period.

(d) *Methods of procurement to be followed*—(1) *Procurement by small purchase procedures.* Small purchase procedures are those relatively simple and informal procurement methods for securing services, supplies, or other property that do not cost more than $25,000 in the aggregate. If small purchase procurements are used, price or rate quotations will be obtained from an adequate number of qualified sources.

(2) Procurement by *sealed bids* (formal advertising). Bids are publicly solicited and a firm-fixed-price contract (lump sum or unit price) is awarded to the responsible bidder whose bid, conforming with all the material terms and conditions of the invitation for bids, is the lowest in price. The sealed bid method is the preferred method for procuring construction, if the conditions in § 92.36(d)(2)(i) apply.

(i) In order for sealed bidding to be feasible, the following conditions should be present:

(A) A complete, adequate, and realistic specification or purchase description is available;

(B) Two or more responsible bidders are willing and able to compete effectively for the business; and

(C) The procurement lends itself to a firm fixed price contract and the selection of the successful bidder can be made principally on the basis of price.

(ii) If sealed bids are used, the following requirements apply:

(A) The invitation for bids will be publicly advertised and bids shall be solicited from an adequate number of known suppliers, providing them sufficient time prior to the date set for opening the bids;

(B) The invitation for bids, which will include any specifications and pertinent attachments, shall define the items or services in order for the bidder to properly respond;

(C) All bids will be publicly opened at the time and place prescribed in the invitation for bids;

(D) A firm fixed-price contract award will be made in writing to the lowest responsive and responsible bidder. Where specified in bidding documents, factors such as discounts, transportation cost, and life cycle costs shall be considered in determining which bid is lowest. Payment discounts will only be used to determine the low bid when prior experience indicates that such discounts are usually taken advantage of; and

(E) Any or all bids may be rejected if there is a sound documented reason.

(3) Procurement by *competitive proposals*. The technique of competitive proposals is normally conducted with more than one source submitting an offer, and either a fixed-price or cost-reimbursement type contract is awarded. It is generally used when conditions are not appropriate for the use of sealed bids. If this method is used, the following requirements apply:

(i) Requests for proposals will be publicized and identify all evaluation factors and their relative importance. Any response to publicized requests for proposals shall be honored to the maximum extent practical;

(ii) Proposals will be solicited from an adequate number of qualified sources;

(iii) Grantees and subgrantees will have a method for conducting technical evaluations of the proposals received and for selecting awardees;

(iv) Awards will be made to the responsible firm whose proposal is most advantageous to the program, with price and other factors considered; and

(v) Grantees and subgrantees may use competitive proposal procedures for qualifications-based procurement of architectural/engineering (A/E) professional services whereby competitors' qualifications are evaluated and the most qualified competitor is selected, subject to negotiation of fair and reasonable compensation. The method, where price is not used as a selection factor, can only be used in procurement of A/E professional services. It cannot be used to purchase other types of services though A/E firms are a potential source to perform the proposed effort.

(4) Procurement by *noncompetitive proposals* is procurement through solicitation of a proposal from only one source, or after solicitation of a number of sources, competition is determined inadequate.

(i) Procurement by noncompetitive proposals may be used only when the award of a contract is infeasible under small purchase procedures, sealed bids or competitive proposals and one of the following circumstances applies:

(A) The item is available only from a single source;

(B) The public exigency or emergency for the requirement will not permit a delay resulting from competitive solicitation.

(C) The awarding agency authorizes noncompetitive proposals; or

(D) After solicitation of a number of sources, competition is determined inadequate.

(ii) Cost analysis, i.e., verifying the proposed cost data, the projections of the data, and the evaluation of the specific elements of costs and profit, is required.

(iii) Grantees and subgrantees may be required to submit the proposed procurement to the awarding agency for pre-award review in accordance with paragraph (g) of this section.

(e) *Contracting with small and minority firms, women's business enterprise and labor surplus area firms.* (1) The grantee and subgrantee will take all necessary affirmative steps to assure that minority firms, women's business enterprises, and labor surplus area firms are used when possible.

(2) Affirmative steps shall include:

(i) Placing qualified small and minority businesses and women's business enterprises on solicitation lists;

(ii) Assuring that small and minority businesses, and women's business enterprises are solicited whenever they are potential sources;

(iii) Dividing total requirements, when economically feasible, into smaller tasks or quantities to permit maximum participation by small and minority business, and women's business enterprises;

(iv) Establishing delivery schedules, where the requirement permits, which encourage participation by small and minority business, and women's business enterprises;

(v) Using the services and assistance of the Small Business Administration, and the Minority Business Development Agency of the Department of Commerce; and

(vi) Requiring the prime contractor, if subcontracts are to be let, to take the affirmative steps listed in paragraphs (e)(2) (i) through (v) of this section.

(f) *Contract cost and price.* (1) Grantees and subgrantees must perform a cost or price analysis in connection with every procurement action including contract modifications. The method and degree of analysis is dependent on the facts surrounding the particular procurement situation, but as a starting point, grantees must make independent estimates before receiving bids or proposals. A cost analysis must be performed when the offeror is required to submit the elements of his estimated cost, e.g., under professional, consulting, and architectural engineering services contracts. A cost analysis will be necessary when adequate price competition is lacking, and for sole source procurements, including contract modifications or change orders, unless price resonableness can be established on the basis of a catalog or market price of a commercial product sold in substantial quantities to the general public or based on prices set by law or regulation. A price analysis will be used in all other instances to determine the reasonableness of the proposed contract price.

(2) Grantees and subgrantees will negotiate profit as a separate element of the price for each contract in which there is no price competition and in all cases where cost analysis is performed. To establish a fair and reasonable profit, consideration will be given to the complexity of the work to be performed, the risk borne by the contractor, the contractor's investment, the amount of subcontracting, the quality of its record of past performance, and industry profit rates in the surrounding geographical area for similar work.

(3) Costs or prices based on estimated costs for contracts under grants will be allowable only to the extent that costs incurred or cost estimates included in negotiated prices are consistent with Federal cost principles (see § 92.22). Grantees may reference their own cost principles that comply with the applicable Federal cost principles.

(4) The cost plus a percentage of cost and percentage of construction cost methods of contracting shall not be used.

(g) *Awarding agency review.* (1) Grantees and subgrantees must make available, upon request of the awarding agency, technical specifications on proposed procurements where the awarding agency believes such review is needed to ensure that the item and/or service specified is the one being proposed for purchase. This review generally will take place prior to the time the specification is incorporated into a solicitation document. However, if the grantee or subgrantee desires to have the review accomplished after a solication has been developed, the awarding agency may still review the specifications, with such review usually limited to the technical aspects of the proposed purchase.

(2) Grantees and subgrantees must on request make available for awarding agency pre-award review procurement documents, such as requests for proposals or invitations for bids, independent cost estimates, etc., when:

(i) A grantee's or subgrantee's procurement procedures or operation fails to comply with the procurement standards in this seciton; or

(ii) The procurement is expected to exceed $25,000 and is to be awarded without competition or only one bid or offer is received in response to a solicitation; or

(iii) The procurement, which is expected to exceed $25,000, specifies a "brand name" product; or

(iv) The proposed award over $25,000 is to be awarded to other than the apparent low bidder under a sealed bid procurement; or

(v) A proposed contract modification changes the scope of a contract or increases the contract amount by more than $25,000.

(3) A grantee or subgrantee will be exempt from the pre-award review in paragraph (g)(2) of this section if the awarding agency determines that its procurement systems comply with the standards of this section.

(i) A grantee or subgrantee may request that its procurement system be reviewed by the awarding agency to determine whether its system meets these standards in order for its system to be certified. Generally, these reviews shall occur where there is a continuous high-dollar funding, and third-party contracts are awarded on a regular basis;

(ii) A grantee or subgrantee may self-certify its procurement system. Such self-certification shall not limit the awarding agency's right to survey the system. Under a self-certification procedure, awarding agencies may wish to rely on written assurances from the grantee or subgrantee that it is complying with these standards. A grantee or subgrantee will cite specific procedures, regulations, standards, etc., as being in compliance with these requirements and have its system available for review.

(h) *Bonding requirements.* For construction or facility improvement contracts or subconstracts exceeding $100,000, the awarding agency may accept the bonding policy and requirements of the grantee or subgrantee provided the awarding agency has made a determination that the awarding agency's interest is adequately protected. If such a determination has not been made, the minimum requirements shall be as follows:

(1) *A bid guarantee from each bidder equivalent to five percent of the bid price.* The "bid guarantee" shall consist of a firm commitment such as a bid bond, certified check, or other negotiable instrument accompanying a bid as assurance that the bidder will, upon acceptance of his bid, execute such contractual documents as may be required within the time specified.

(2) *A performance bond on the part of the contractor for 100 percent of the contract price.* A "performance bond" is one executed in connection with a contract to secure fulfillment of all the contractor's obligations under such contract.

(3) *A payment bond on the part of the contractor for 100 percent of the contract price.* A "payment bond" is one executed in connection with a contract to assure payment as required by law of all persons supplying labor and material in the execution of the work provided for in the contract.

(i) *Contract provisions.* A grantee's and subgrantee's contracts must contain provisions in paragraph (i) of this section. Federal agencies are permitted to require changes, remedies, changed conditions, access and records retention, suspension of work, and other clauses approved by the Office of Procurement Policy.

(1) Administrative, contractual, or legal remedies in instances where contractors violate or breach contract terms, and provide for such sanctions and penalties as may be appropriate (Contracts other than small purchases).

(2) Termination for cause and for convenience by the grantee or subgrantee including the manner by which it will be effected and the basis for settlement (All contracts in excess of $10,000).

(3) Compliance with Executive Order 11246 of September 24, 1965 entitled "Equal Employment Opportunity," as amended by Executive Order 11375 of October 13, 1967 and as supplemented in Department of Labor regulations (41 CFR Chapter 60) (All construction contracts awarded in excess of $10,000 by grantees and their contractors or subgrantees).

(4) Compliance with the Copeland "Anti-Kickback" Act (18 U.S.C. 874) as supplemented in Department of Labor regulations (29 CFR Part 3) (All contracts and subgrants for construction or repair).

(5) Compliance with the Davis-Bacon Act (40 U.S.C. 276a to a-7) as supplemented by Department of Labor regulations (29 CFR Part 5) (Construction contracts in excess of $2,000 awarded by grantees and subgrantees when required by Federal grant program legislation).

(6) Compliance with sections 103 and 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 327-330) as supplemented by Department of Labor regulations (29 CFR Part 5). (Construction contracts awarded by grantees and subgrantees in excess of $2,000, and in excess of $2,500 for other contracts which involve the employment of mechanics or laborers)

(7) Notice of awarding agency requirements and regulations pertaining to reporting.

(8) Notice of awarding agency requirements and regulations pertaining to patent rights with respect to any discovery or invention which arises or is developed in the course of or under such contract.

(9) Awarding agency requirements and regulations pertaining to copyrights and rights in data.

(10) Access by the grantee, the subgrantee, the Federal grantor agency, the Comptroller General of the United States, or any of their duly authorized representatives to any books, documents, papers, and records of the contractor which are directly pertinent to that specific contract for the purpose of making audit, examination, excerpts, and transcriptions.

(11) Retention of all required records for three years after grantees or subgrantees make final payments and all other pending matters are closed.

(12) Compliance with all applicable standards, orders, or requirements issued under section 306 of the Clear Air Act (42 U.S.C. 1857(h)), section 508 of the Clean Water Act (33 U.S.C. 1368), Executive Order 11738, and Environmental Protection Agency regulations (40 CFR Part 15) (Contracts, subcontracts, and subgrants of amounts in excess of $100,000).

(13) Mandatory standards and policies relating to energy efficiency which are contained in the state energy conservation plan issued in compliance with the Energy Policy and Conservation Act (Pub. L. 94-163).

§ 92.37 Subgrants.

(a) *States.* States shall follow state law and procedures when awarding and administering subgrants (whether on a cost reimbursement or fixed amount basis) of financial assistance to local and Indian tribal governments. States shall:

(1) Ensure that every subgrant includes any clauses required by Federal statute and executive orders and their implementing regulations;

(2) Ensure that subgrantees are aware of requirements imposed upon them by Federal statute and regulation;

(3) Ensure that a provision for compliance with § 92.42 is placed in every cost reimbursement subgrant; and

(4) Conform any advances of grant funds to subgrantees substantially to the same standards of timing and amount that apply to cash advances by Federal agencies.

(b) *All other grantees.* All other grantees shall follow the provisions of this part which are applicable to awarding agencies when awarding and administering subgrants (whether on a cost reimbursement or fixed amount basis) of financial assistance to local and Indian tribal governments. Grantees shall:

(1) Ensure that every subgrant includes a provision for compliance with this part;

(2) Ensure that every subgrant includes any clauses required by Federal statute and executive orders and their implementing regulations; and

(3) Ensure that subgrantees are aware of requirements imposed upon them by Federal statutes and regulations.

(c) *Exceptions.* By their own terms, certain provisions of this part do not apply to the award and administration of subgrants:

(1) Section 92.10;

(2) Section 92.11;

(3) The letter-of-credit procedures specified in Treasury Regulations at 31 CFR Part 205, cited in § 92.21; and

(4) Section 92.50.

REPORTS, RECORDS, RETENTION, AND ENFORCEMENT

§ 92.40 Monitoring and reporting program performance.

(a) *Monitoring by grantees.* Grantees are responsible for managing the day-to-day operations of grant and subgrant supported activities. Grantees must monitor grant and subgrant supported activities to assure compliance with applicable Federal requirements and that performance goals are being achieved. Grantee monitoring must cover each program, function or activity.

(b) *Nonconstruction performance reports.* The Federal agency may, if it decides that performance information available from subsequent applications contains sufficient information to meet its programmatic needs, require the grantee to submit a performance report only upon expiration or termination of grant support. Unless waived by the Federal agency this report will be due on the same date as the final Financial Status Report.

(1) Grantees shall submit annual performance reports unless the awarding agency requires quarterly or semi-annual reports. However, performance reports will not be required more frequently than quarterly. Annual reports shall be due 90 days after the grant year, quarterly or semi-annual reports shall be due 30 days after the reporting period. The final performance report will be due 90 days after the expiration or termination of grant support. If a justified request is submitted by a grantee, the Federal agency may extend the due date for any performance report. Additionally, requirements for unnecessary performance reports may be waived by the Federal agency.

(2) Performance reports will contain, for each grant, brief information on the following:

(i) A comparison of actual accomplishments to the objectives established for the period. Where the output of the project can be quantified, a computation of the cost per unit of output may be required if that information will be useful.

(ii) The reasons for slippage if established objectives were not met.

(iii) Additional pertinent information including, when appropriate, analysis and explanation of cost overruns or high unit costs.

(3) Grantees will not be required to submit more than the original and two copies of performance reports.

(4) Grantees will adhere to the standards in this section in prescribing performance reporting requirements for subgrantees.

(c) *Construction performance reports.* For the most part, on-site technical inspections and certified percentage-of-completion data are relied on heavily by Federal agencies to monitor progress under construction grants and subgrants. The Federal agency will require additional formal performance reports only when considered necessary, and never more frequently than quarterly.

(d) *Significant developments.* Events may occur between the scheduled performance reporting dates which have significant impact upon the grant or subgrant supported activity. In such cases, the grantee must inform the Federal agency as soon as the following types of conditions become known:

(1) Problems, delays, or adverse conditions which will materially impair the ability to meet the objective of the award. This disclosure must include a statement of the action taken, or contemplated, and any assistance needed to resolve the situation.

(2) Favorable developments which enable meeting time schedules and objectives sooner or at less cost than anticipated or producing more beneficial results than originally planned.

(e) Federal agencies may make site visits as warranted by program needs.

(f) *Waivers, extensions.* (1) Federal agencies may waive any performance report required by this part if not needed.

(2) The grantee may waive any performance report from a subgrantee when not needed. The grantee may extend the due date for any performance report from a subgrantee if the grantee will still be able to meet its performance reporting obligations to the Federal agency.

§ 92.41 Financial reporting.

(a) *General.* (1) Except as provided in paragraphs (a) (2) and (5) of this section, grantees will use only the forms specified in paragraphs (a) through (e) of this section, and such supplementary or other forms as may from time to time be authorized by OMB, for:

(i) Submitting financial reports to Federal agencies, or

(ii) Requesting advances or reimbursements when letters of credit are not used.

(2) Grantees need not apply the forms prescribed in this section in dealing with their subgrantees. However, grantees shall not impose more burdensome requirements on subgrantees.

(3) Grantees shall follow all applicable standard and supplemental Federal agency instructions approved by OMB to the extend required under the Paperwork Reduction Act of 1980 for use in connection with forms specified in paragraphs (b) through (e) of this section. Federal agencies may issue substantive supplementary instruc-

tions only with the approval of OMB. Federal agencies may shade out or instruct the grantee to disregard any line item that the Federal agency finds unnecessary for its decisionmaking purposes.

(4) Grantees will not be required to submit more than the original and two copies of forms required under this part.

(5) Federal agencies may provide computer outputs to grantees to expedite or contribute to the accuracy of reporting. Federal agencies may accept the required information from grantees in machine usable format or computer printouts instead of prescribed forms.

(6) Federal agencies may waive any report required by this section if not needed.

(7) Federal agencies may extend the due date of any financial report upon receiving a justified request from a grantee.

(b) *Financial Status Report*—(1) *Form.* Grantees will use Standard Form 269 or 269A, Financial Status Report, to report the status of funds for all nonconstruction grants and for construction grants when required in accordance with § 92.41(e)(2)(iii).

(2) *Accounting basis.* Each grantee will report program outlays and program income on a cash or accrual basis as prescribed by the awarding agency. If the Federal agency requires accrual information and the grantee's accounting records are not normally kept on the accural basis, the grantee shall not be required to convert its accounting system but shall develop such accrual information through and analysis of the documentation on hand.

(3) *Frequency.* The Federal agency may prescribe the frequency of the report for each project or program. However, the report will not be required more frequently than quarterly. If the Federal agency does not specify the frequency of the report, it will be submitted annually. A final report will be required upon expiration or termination of grant support.

(4) *Due date.* When reports are required on a quarterly or semiannual basis, they will be due 30 days after the reporting period. When required on an annual basis, they will be due 90 days after the grant year. Final reports will be due 90 days after the expiration or termination of grant support.

(c) *Federal Cash Transactions Report*—(1) *Form.* (i) For grants paid by letter or credit, Treasury check advances or electronic transfer of funds, the grantee will submit the Standard Form 272, Federal Cash Transactions Report, and when necessary, its continuation sheet, Standard Form 272a, unless the terms of the award exempt the grantee from this requirement.

(ii) These reports will be used by the Federal agency to monitor cash advanced to grantees and to obtain disbursement or outlay information for each grant from grantees. The format of the report may be adapted as appropriate when reporting is to be accomplished with the assistance of automatic data processing equipment provided that the information to be submitted is not changed in substance.

(2) *Forecasts of Federal cash requirements.* Forecasts of Federal cash requirements may be required in the "Remarks" section of the report.

(3) *Cash in hands of subgrantees.* When considered necessary and feasible by the Federal agency, grantees may be required to report the amount of cash advances in excess of three days' needs in the hands of their subgrantees or contractors and to provide short narrative explanations of actions taken by the grantee to reduce the excess balances.

(4) *Frequency and due date.* Grantees must submit the report no later than 15 working days following the end of each quarter. However, where an advance either by letter of credit or electronic transfer of funds is authorized at an annualized rate of one million dollars or more, the Federal agency may require the report to be submitted within 15 working days following the end of each month.

(d) *Request for advance or reimbursement*—(1) *Advance payments.* Requests for Treasury check advance payments will be submitted on Standard Form 270, Request for Advance or Reimbursement. (This form will not be used for drawdowns under a letter of credit, electronic funds transfer or when Treasury check advance payments are made to the grantee automatically on a predetermined basis.)

(2) *Reimbursements.* Requests for reimbursement under nonconstruction grants will also be submitted on Standard Form 270. (For reimbursement requests under construction grants, see paragraph (e)(1) of this section.)

(3) The frequency for submitting payment requests is treated in § 92.41(b)(3).

(e) *Outlay report and request for reimbursement for construction programs.* (1) *Grants that support construction activities paid by reimbursement method.* (i) Requests for reimbursement under construction grants will be submitted on Standard Form 271, Outlay Report and Request for Reimbursement for Construction Programs. Federal agencies may, however, prescribe the Request for Advance or Reimbursement form, specified in § 92.41(d), instead of this form.

(ii) The frequency for submitting reimbursement requests is treated in § 92.41(b)(3).

(2) *Grants that support construction activities paid by letter of credit, electronic funds transfer or Treasury check advance.* (i) When a construction grant is paid by letter of credit, electronic funds transfer or Treasury check advances, the grantee will report its outlays to the Federal agency using Standard Form 271, Outlay Report and Request for Reimbursement for Construction Programs. The Federal agency will provide any necessary special instruction. However, frequency and due date shall be governed by § 92.41(b) (3) and (4).

(ii) When a construction grant is paid by Treasury check advances based on periodic requests from the grantee, the advances will be requested on the form specified in § 92.41(d).

(iii) The Federal agency may substitute the Financial Status Report specified in § 92.41(b) for the Outlay Report and Request for Reimbursement for Construction Programs.

(3) *Accounting basis.* The accounting basis for the Outlay Report and Request for Reimbursement for Construction Programs shall be governed by § 92.41(b)(2).

§ 92.42 Retention and access requirements for records.

(a) *Applicability.* (1) This section applies to all financial and programmatic records, supporting documents, statistical records, and other records of grantees or subgrantees which are:

(i) Required to be maintained by the terms of this part, program regulations or the grant agreement, or

(ii) Otherwise reasonably considered as pertinent to program regulations or the grant agreement.

(2) This section does not apply to records maintained by contractors or subcontractors. For a requirement to place a provision concerning records in certain kinds of contracts, see § 92.36(i)(10).

(b) *Length of retention period.* (1) Except as otherwise provided, records must be retained for three years from the starting date specified in paragraph (c) of this section.

(2) If any litigation, claim, negotiation, audit or other action involving the records has been started before the expiration of the 3-year period, the records must be retained until completion of the action and resolution of all issues which arise from it, or until the end of the regular 3-year period, whichever is later.

(3) To avoid duplicate recordkeeping, awarding agencies may make special arrangements with grantees and subgrantees to retain any records which are continuously needed for joint use. The awarding agency will request transfer of records to its custody when it determines that the records possess long-term retention value. When the records are transferred to or maintained by the Federal agency, the 3-year retention requirement is not applicable to the grantee or subgrantee.

(c) *Starting date of retention period*—(1) *General.* When grant support is continued or renewed at annual or other intervals, the retention period for the records of each funding period starts on the day the grantee or subgrantee submits to the awarding agency its single or last expenditure report for that period. However, if grant support is continued or renewed quarterly, the retention period for each year's records starts on the day the grantee submits its expenditure report for the last quarter of the Federal fiscal year. In all other cases, the retention period starts on the day the grantee submits its final expenditure report. If an expenditure report has been waived, the retention period starts on the day the report would have been due.

(2) *Real property and equipment records.* The retention period for real property and equipment records starts from the date of the disposition or replacement or transfer at the direction of the awarding agency.

(3) *Records for income transactions after grant or subgrant support.* In some cases grantees must report income after the period of grant support. Where there is such a requirement, the retention period for the records pertaining to the earning of the income starts from the end of the grantee's fiscal year in which the income is earned.

(4) *Indirect cost rate proposals, cost allocations plans, etc.* This paragraph applies to the following types of documents, and their supporting records: indirect cost rate computations or proposals, cost allocation plans, and any similar accounting computations of the rate at which a particular group of costs is chargeable (such as computer usage chargeback rates or composite fringe benefit rates).

(i) *If submitted for negotiation.* If the proposal, plan, or other computation is required to be submitted to the Federal Government (or to the grantee) to form the basis for negotiation of the rate, then the 3-year retention period for its supporting records starts from the date of such submission.

(ii) *If not submitted for negotiation.* If the proposal, plan, or other computation is not required to be submitted to the Federal Government (or to the grantee) for negotiation purposes, then the 3-year retention period for the proposal plan, or computation and its supporting records starts from end of the fiscal year (or other accounting period) covered by the proposal, plan, or other computation.

(d) *Substitution of microfilm.* Copies made by microfilming, photocopying, or similar methods may be substituted for the original records.

(e) *Access to records*—(1) *Records of grantees and subgrantees.* The awarding agency and the Comptroller General of the United States, or any of their authorized representatives, shall have the right of access to any pertinent books, documents, papers, or other records of grantees and subgrantees which are pertinent to the grant, in order to make audits, examinations, excerpts, and transcripts.

(2) *Expiration of right of access.* The rights of access in this section must not be limited to the required retention period but shall last as long as the records are retained.

(f) *Restrictions on public access.* The Federal Freedom of Information Act (5 U.S.C. 552) does not apply to records Unless required by Federal, State, or local law, grantees and subgrantees are not required to permit public access to their records.

§ 92.43 Enforcement.

(a) *Remedies for noncompliance.* If a grantee or subgrantee materially fails to comply with any term of an award, whether stated in a Federal statute or regulation, an assurance, in a State plan or application, a notice of award, or elsewhere, the awarding agency may take one or more of the following actions, as appropriate in the circumstances:

(1) Temporarily withhold cash payments pending correction of the deficiency by the grantee or subgrantee or more severe enforcement action by the awarding agency,

(2) Disallow (that is, deny both use of funds and matching credit for) all or part of the cost of the activity or action not in compliance,

(3) Wholly or partly suspend or terminate the current award for the grantee's or subgrantee's program,

(4) Withhold further awards for the program, or

(5) Take other remedies that may be legally available.

(b) *Hearings, appeals.* In taking an enforcement action, the awarding agency will provide the grantee or subgrantee an opportunity for such hearing, appeal, or other administrative proceeding to which the grantee or subgrantee is entitled under any statute or regulation applicable to the action involved.

(c) *Effects of suspension and termination.* Costs of grantee or subgrantee resulting from obligations incurred by the grantee or subgrantee during a suspension or after termination of an award are not allowable unless the awarding agency expressly authorizes them in the notice of suspension or termination or subsequently. Other grantee or subgrantee costs during suspension or after termination which are necessary and not reasonably avoidable are allowable if:

(1) The costs result from obligations which were properly incurred by the grantee or subgrantee before the effective date of suspension or termination, are not in anticipation of it, and, in the case of a termination, are noncancellable, and,

(2) The costs would be allowable if the award were not suspended or expired normally at the end of the funding period in which the termination takes effect.

(d) *Relationship to debarment and suspension.* The enforcement remedies identified in this section, including suspension and termination, do not preclude grantee or subgrantee from being subject to "Debarment and Suspension" under E.O. 12549 (see § 92.35).

§ 92.44 Termination for convenience.

Except as provided in § 92.43 awards may be terminated in whole or in part only as follows:

(a) By the awarding agency with the consent of the grantee or subgrantee in which case the two parties shall agree upon the termination conditions, including the effective date and in the case of partial termination, the portion to be terminated, or

(b) By the grantee or subgrantee upon written notification to the awarding agency, setting forth the reasons for such termination, the effective date, and in the case of partial termination, the portion to be terminated. However, if, in the case of a partial termination, the awarding agency determines that the remaining portion of the award will not accomplish the purposes for which the award was made, the awarding agency may terminate the award in its entirety under either § 92.43 or paragraph (a) of this section.

Subpart D—After-The-Grant Requirements

§ 92.50 Closeout.

(a) *General.* The Federal agency will close out the award when it determines that all applicable administrative actions and all required work of the grant has been completed.

(b) *Reports.* Within 90 days after the expiration or termination of the grant, the grantee must submit all financial, performance, and other reports required as a condition of the grant. Upon request by the grantee, Federal agencies may extend this timeframe. These may include but are not limited to:

(1) *Final performance or progress report.*

(2) *Financial Status Report (SF 269) or Outlay Report and Request for Reimbursement for Construction Programs (SF-271) (as applicable).*

(3) *Final request for payment (SF-270) (if applicable).*

(4) *Invention disclosure (if applicable).*

(5) *Federally-owned property report:* In accordance with § 92.32(f), a grantee must submit an inventory of all federally owned property (as distinct from property acquired with grant funds) for which it is accountable and request disposition instructions from the Federal agency of property no longer needed.

(c) *Cost adjustment.* The Federal agency will, within 90 days after receipt of reports in paragraph (b) of this section, make upward or downward adjustments to the allowable costs.

(d) *Cash adjustments.* (1) The Federal agency will make prompt payment to the grantee for allowable reimbursable costs.

(2) The grantee must immediately refund to the Federal agency any balance of unobligated (unencumbered) cash advanced that is not authorized to be retained for use on other grants.

§ 92.51 Later disallowances and adjustments.

The closeout of a grant does not affect:

(a) The Federal agency's right to disallow costs and recover funds on the basis of a later audit or other review;

(b) The grantee's obligation to return any funds due as a result of later refunds, corrections, or other transactions;

(c) Records retention as required in § 92.42;

(d) Property management requirements in §§ 92.31 and 92.32; and

(e) Audit requirements in § 92.26.

§ 92.52 Collection of amounts due.

(a) Any funds paid to a grantee in excess of the amount to which the grantee is finally determined to be entitled under the terms of the award constitute a debt to the Federal Government. If not paid within a reasonable period after demand, the Federal agency may reduce the debt by:

(1) Making an adminstrative offset against other requests for reimbursements,

(2) Withholding advance payments otherwise due to the grantee, or

(3) Other action permitted by law.

(b) Except where otherwise provided by statutes or regulations, the Federal agency will charge interest on an overdue debt in accordance with the Federal Claims Collection Standards (4 CFR Ch. II). The date from which interest is computed is not extended by litigation or the filing of any form of appeal.

Subpart E—Entitlement [Reserved]

PART 93—NEW RESTRICTIONS ON LOBBYING

Subpart A—General

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APPENDIX A TO PART 93—CERTIFICATION REGARDING LOBBYING
APPENDIX B TO PART 93—DISCLOSURE FORM TO REPORT LOBBYING

AUTHORITY: Section 319, Public Law 101-121 (31 U.S.C. 1352); 5 U.S.C. 301.

CROSS REFERENCE: See also Office of Management and Budget notice published at 54 FR 52306, December 20, 1989.

SOURCE: 55 FR 6754, Feb. 26, 1990, unless otherwise noted.

Subpart A—General

§ 93.100 Conditions on use of funds.

(a) No appropriated funds may be expended by the recipient of a Federal contract, grant, loan, or cooperative ageement to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions: the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(b) Each person who requests or receives from an agency a Federal contract, grant, loan, or cooperative agreement shall file with that agency a certification, set forth in Appendix A to this part, that the person has not made, and will not make, any payment prohibited by paragraph (a) of this section.

(c) Each person who requests or receives from an agency a Federal contract, grant, loan, or a cooperative agreement shall file with that agency a disclosure form, set forth in Appendix B to this part, if such person has made or has agreed to make any payment using nonappropriated funds (to include profits from any covered Federal action), which would be prohibited under paragraph (a) of this section if paid for with appropriated funds.

(d) Each person who requests or receives from an agency a commitment providing for the United States to insure or guarantee a loan shall file with that agency a statement, set forth in Appendix A to this part, whether that person has made or has agreed to make any payment to influence or attempt to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with that loan insurance or guarantee.

(e) Each person who requests or receives from an agency a commitment providing for the United States to insure or guarantee a loan shall file with that agency a disclosure form, set forth in Appendix B to this part, if that person has made or has agreed to make any payment to influence or attempt to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with that loan insurance or guarantee.

§ 93.105 Definitions.

For purposes of this part:

(a) *Agency,* as defined in 5 U.S.C. 552(f), includes Federal executive departments and agencies as well as independent regulatory commissions and Government corporations, as defined in 31 U.S.C. 9101(1).

(b) *Covered Federal action* means any of the following Federal actions:

(1) The awarding of any Federal contract;

(2) The making of any Federal grant;

(3) The making of any Federal loan;

(4) The entering into of any cooperative agreement; and,

(5) The extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

Covered Federal action does not include receiving from an agency a commitment providing for the United States to insure or guarantee a loan. Loan guarantees and loan insurance are addressed independently within this part.

(c) *Federal contract* means an acquisition contract awarded by an agency, including those subject to the Federal Acquisition Regulation (FAR), and any other acquisition contract for real or personal property or services not subject to the FAR.

(d) *Federal cooperative agreement* means a cooperative agreement entered into by an agency.

(e) *Federal grant* means an award of financial assistance in the form of money, or property in lieu of money, by the Federal Government or a direct appropriation made by law to any person. The term does not include technical assistance which provides services instead of money, or other assistance in the form of revenue sharing, loans, loan guarantees, loan insurance, interest subsidies, insurance, or direct United States cash assistance to an individual.

(f) *Federal loan* means a loan made by an agency. The term does not include loan guarantee or loan insurance.

(g) *Indian tribe* and *tribal organization* have the meaning provided in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450B). Alaskan Natives are included under the definitions of Indian tribes in that Act.

(h) *Influencing or attempting to influence* means making, with the intent to influence, any communication to or appearance before an officer or employee or any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any covered Federal action.

(i) *Loan guarantee* and *loan insurance* means an agency's guarantee or insurance of a loan made by a person.

(j) *Local government* means a unit of government in a State and, if chartered, established, or otherwise recognized by a State for the performance of a governmental duty, including a local public authority, a special district, an intrastate district, a council of governments, a sponsor group representative organization, and any other instrumentality of a local government.

(k) *Officer or employee of an agency* includes the following individuals who are employed by an agency:

(1) An individual who is appointed to a position in the Government under title 5, U.S. Code, including a position under a temporary appointment;

(2) A member of the uniformed services as defined in section 101(3), title 37, U.S. Code;

(3) A special Government employee as defined in section 202, title 18, U.S. Code; and,

(4) An individual who is a member of a Federal advisory committee, as defined by the Federal Advisory Committee Act, title 5, U.S. Code appendix 2.

(l) *Person* means an individual, corporation, company, association, authority, firm, partnership, society, State, and local government, regardless of whether such entity is operated for profit or not for profit. This term excludes an Indian tribe, tribal organization, or any other Indian organization with respect to expenditures specifically permitted by other Federal law.

(m) *Reasonable compensation* means, with respect to a regularly employed officer or employee of any person, compensation that is consistent with the normal compensation for such officer or employee for work that is not furnished to, not funded by, or not furnished in cooperation with the Federal Government.

(n) *Reasonable payment* means, with respect to perfessional and other technical services, a payment in an amount that is consistent with the amount normally paid for such services in the private sector.

(o) *Recipient* includes all contractors, subcontractors at any tier, and subgrantees at any tier of the recipient of funds received in connection with a Federal contract, grant, loan, or cooperative agreement. The term excludes an Indian tribe, tribal organization, or any other Indian organization with respect to expenditures specifically permitted by other Federal law.

(p) *Regularly employed* means, with respect to an officer or employee of a person requesting or receiving a Federal contract, grant, loan, or cooperative agreement or a commitment providing for the United States to insure or guarantee a loan, an officer or employee who is employed by such person for at least 130 working days within one year immediately preceding the date of the submission that initiates agency consideration of such person for receipt of such contract, grant, loan, cooperative agreement, loan insurance commitment, or loan guarantee commitment. An officer or employee who is employed by such person for less than 130 working days within one year immediately preceding the date of the submission that initiates agency consideration of such person shall be considered to be regularly employed as soon as he or she is employed by such person for 130 working days.

(q) *State* means a State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, a territory or possession of the United States, an agency or instrumentality of a State, and a multi-State, regional, or interstate entity having governmental duties and powers.

§ 93.110 Certification and disclosure.

(a) Each person shall file a certification, and a disclosure form, if required, with each submission that initiates agency consideration of such person for:

(1) Award of a Federal contract, grant, or cooperative agreement exceeding $100,000; or

(2) An award of a Federal loan or a commitment providing for the United States to insure or guarantee a loan exceeding $150,000.

(b) Each person shall file a certification, and a disclosure form, if required, upon receipt by such person of:

(1) A Federal contract, grant, or cooperative agreement exceeding $100,000; or

(2) A Federal loan or a commitment providing for the United States to insure or guarantee a loan exceeding $150,000,

unless such person previously filed a certification, and a disclosure form, if required, under paragraph (a) of this section.

(c) Each person shall file a disclosure form at the end of each calendar quarter in which there occurs any event that requires disclosure or that materially affects the accuracy of the information contained in any disclosure form previously filed by such person under paragraphs (a) or (b) of this section. An event that materially affects the accuracy of the information reported includes:

(1) A cumulative increase of $25,000 or more in the amount paid or expected to be paid for influencing or attempting to influence a covered Federal action; or

(2) A change in the person(s) or individual(s) influencing or attempting to influence a covered Federal action; or,

(3) A change in the officer(s), employee(s), or Member(s) contacted to influence or attempt to influence a covered Federal action.

(d) Any person who requests or receives from a person referred to in paragraphs (a) or (b) of this section:

(1) A subcontract exceeding $100,000 at any tier under a Federal contract;

(2) A subgrant, contract, or subcontract exceeding $100,000 at any tier under a Federal grant;

(3) A contract or subcontract exceeding $100,000 at any tier under a Federal loan exceeding $150,000; or,

(4) A contract or subcontract exceeding $100,000 at any tier under a Federal cooperative agreement,

shall file a certification, and a disclosure form, if required, to the next tier above.

(e) All disclosure forms, but not certifications, shall be forwarded from tier to tier until received by the person referred to in paragraphs (a) or (b) of this section. That person shall forward all disclosure forms to the agency.

(f) Any certification or disclosure form filed under paragraph (e) of this section shall be treated as a material representation of fact upon which all receiving tiers shall rely. All liability arising from an erroneous representation shall be borne solely by the tier filing that representation and shall not be shared by any tier to which the erroneous representation is forwarded. Submitting an erroneous certification or disclosure constitutes a failure to file the required certification or disclosure, respectively. If a person fails to file a required certification or disclosure, the United States may pursue all available remedies, including those authorized by section 1352, title 31, U.S. Code.

(g) For awards and commitments in process prior to December 23, 1989, but not made before that date, certifications shall be required at award or commitment, covering activities occurring between December 23, 1989, and the date of award or commitment. However, for awards and commitments in process prior to the December 23, 1989 effective date of these provisions, but not made before December 23, 1989, disclosure forms shall not be required at time of award or commitment but shall be filed within 30 days.

(h) No reporting is required for an activity paid for with appropriated funds if that activity is allowable under either Subpart B or C.

Subpart B—Activities by Own Employees

§ 93.200 Agency and legislative liaison.

(a) The prohibition on the use of appropriated funds, in § 93.100 (a), does not apply in the case of a payment of reasonable compensation made to an officer or employee of a person requesting or receiving a Federal contract, grant, loan, or cooperative agreement if the payment is for agency and legislative liaison activities not directly related to a covered Federal action.

(b) For purposes of paragraph (a) of this section, providing any information specifically requested by an agency or Congress is allowable at any time.

(c) For purposes of paragraph (a) of this section, the following agency and legislative liaison activities are allowable at any time only where they are not related to a specific solicitation for any covered Federal action:

(1) Discussing with an agency (including individual demonstrations) the qualities and characteristics of the person's products or services, conditions or terms of sale, and service capabilities; and,

(2) Technical discussions and other activities regarding the application or adaptation of the person's products or services for an agency's use.

(d) For purposes of paragraph (a) of this section, the following agencies and legislative liaison activities are allowable only where they are prior to formal solicitation of any covered Federal action:

(1) Providing any information not specifically requested but necessary for an agency to make an informed decision about initiation of a covered Federal action;

(2) Technical discussions regarding the preparation of an unsolicited proposal prior to its official submission; and,

(3) Capability presentations by persons seeking awards from an agency pursuant to the provisions of the Small Business Act, as amended by Public Law 95-507 and other subsequent amendments.

(e) Only those activities expressly authorized by this section are allowable under this section.

§ 93.205 Professional and technical services.

(a) The prohibition on the use of appropriated funds, in § 93.100 (a) does not apply in the case of a payment of reasonable compensation made to an officer or employee of a person requesting or receiving a Federal contract, grant, loan, or cooperative agreement or an extension, continuation, renewal, amendment, or modification of a Federal contract, grant, loan, or cooperative agreement if payment is for professional or technical services rendered directly in the preparation, submission, or negotiation of any bid, proposal, or application for that Federal contract, grant, loan, or cooperative agreement or for meeting requirements imposed by or pursuant to law as a condition for receiving that Federal contract, grant, loan, or cooperative agreement.

(b) For purposes of paragraph (a) of this section, "professional and technical services" shall be limited to advice and analysis directly applying any professional or technical discipline. For example, drafting of a legal document accompanying a bid or proposal by a lawyer is allowable. Similarly, technical advice provided by an engineer on the performance or operational capability of a piece of equipment rendered directly in the negotiation of a contract is allowable. However, communications with the intent to influence made by a professional (such as a licensed lawyer) or a technical person (such as a licensed accountant) are not allowable under this section unless they provide advice and analysis directly applying their professional or technical expertise and unless the advice or analysis is rendered directly and solely in the preparation, submission or negotiation of a covered Federal action. Thus, for example, communications with the intent to influence made by a lawyer that do not provide legal advice or analysis directly and solely related to the legal aspects of his or her client's proposal, but generally advocate one proposal over another are not allowable under this section because the lawyer is not providing professional legal services. Similarly, communications with the intent to influence made by an engineer providing an engineering analysis prior to the preparation or submission of a bid or proposal are not allowable under this section since the engineer is providing technical services but not directly in the preparation, submission or negotiation of a covered Federal action.

(c) Requirements imposed by or pursuant to law as a condition for receiving a covered Federal award include those required by law or regulation, or reasonably expected to be required by law or regulation, and any other requirements in the actual award documents.

(d) Only those services expressly authorized by this section are allowable under this section.

§ 93.210 Reporting.

No reporting is required with respect to payments of reasonable compensation made to regularly employed officers or employees of a person.

Subpart C—Activities by Other Than Own Employees

§ 93.300 Professional and technical services.

(a) The prohibition on the use of appropriated funds, in § 93.100 (a) does not apply in the case of any reasonable payment to a person, other than an officer or employee of a person requesting or receiving a covered Federal action, if the payment is for professional or technical services rendered directly in the preparation, submission, or negotiation of any bid, proposal, or application for that Federal contract, grant, loan, or cooperative agreement or for meeting requirements imposed by or pursuant to law as a condition for receiving that Federal contract, grant, loan, or cooperative agreement.

(b) The reporting requirements in § 93.110 (a) and (b) regarding filing a disclosure form by each person, if required, shall not apply with respect to professional or technical services rendered directly in the preparation, submission, or negotiation of any commitment providing for the United States to insure or guarantee a loan.

(c) For purposes of paragraph (a) of this section, "professional and technical services" shall be limited to advice and analysis directly applying any professional or technical discipline. For example, drafting or a legal document accompanying a bid or proposal by a lawyer is allowable. Similarly, technical advice provided by an engineer on the performance or operational capability of a piece of equipment rendered directly in the negotiation of a contract is allowable. However, communications with the intent to influence made by a professional (such as a licensed lawyer) or a technical person (such as a licensed accountant) are not allowable under this section unless they provide advice and analysis directly applying their professional or technical expertise and unless the advice or analysis is rendered directly and solely in the preparation, submission or negotiation of a covered Federal action. Thus, for example, communications with the intent to influence made by a lawyer that do not provide legal advice or analysis directly and solely related to the legal aspects of his or her client's proposal, but generally advocate one proposal over another are not allowable under this section because the lawyer is not providing professional legal services. Similarly, communications with the intent to influence made by an engineer providing an engineering analysis prior to the preparation or submission of a bid or proposal are not allowable under this section since the engineer is providing technical services but not directly in the preparation, submission or negotiation of a covered Federal action.

(d) Requirements imposed by or pursuant to law as a condition for receiving a covered Federal award include those required by law or regulation, or reasonably expected to be required by law or regulation, and any other requirements in the actual award documents.

(e) Persons other than officers or employees of a person requesting or receiving a covered Federal action include consultants and trade associations.

(f) Only those services expressly authorized by this section are allowable under this section.

Subpart D—Penalties and Enforcement

§ 93.400 Penalties.

(a) Any person who makes an expenditure prohibited herein shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such expenditure.

(b) Any person who fails to file or amend the disclosure form (see Appendix B to this part) to be filed or amended if required herein, shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

(c) A filing or amended filing on or after the date on which an administrative action for the imposition of a civil penalty is commenced does not prevent the imposition of such civil penalty for a failure occurring before that date. An administrative action is commenced with respect to a failure when an investigating official determines in writing to commence an investigation of an allegation of such failure.

(d) In determining whether to impose a civil penalty, and the amount of any such penalty, by reason of a violation by any person, the agency shall consider the nature, circumstances, extent, and gravity of the violation, the effect on the ability of such person to continue in business, any prior violations by such person, the degree of culpability of such person, the ability of the person to pay the penalty, and such other matters as may be appropriate.

(e) First offenders under paragraphs (a) or (b) of this section shall be subject to a civil penalty of $10,000, absent aggravating circumstances. Second and subsequent offenses by persons shall be subject to an appropriate civil penalty between $10,000 and $100,000, as determined by the agency head or his or her designee.

(f) An imposition of a civil penalty under this section does not prevent the United States from seeking any other remedy that may apply to the same conduct that is the basis for the imposition of such civil penalty.

§ 93.405 Penalty procedures.

Agencies shall impose and collect civil penalties pursuant to the provisions of the Program Fraud and Civil Remedies Act, 31 U.S.C. sections 3803 (except subsection (c)), 3804, 3805, 3806, 3807, 3808, and 3812, insofar as these provisions are not inconsistent with the requirements herein.

§ 93.410 Enforcement.

The head of each agency shall take such actions as are necessary to ensure that the provisions herein are vigorously implemented and enforced in that agency.

Subpart E—Exemptions

§ 93.500 Secretary of Defense.

(a) The Secretary of Defense may exempt, on a case-by-case basis, a covered Federal action from the prohibition whenever the Secretary determines, in writing, that such an exemption is in the national interest. The Secretary shall transmit a copy of each such written exemption to Congress immediately after making such a determination.

(b) The Department of Defense may issue supplemental regulations to implement paragraph (a) of this section.

Subpart F—Agency Reports

§ 93.600 Semi-annual compilation.

(a) The head of each agency shall collect and compile the disclosure reports (see Appendix B to this part) and, on May 31 and November 30 of each year, submit to the Secretary of the Senate and the Clerk of the House of Representatives a report containing a compilation of the information contained in the disclosure reports received during the six-month period ending on March 31 or September 30, respectively, of that year.

(b) The report, including the compilation, shall be available for public inspection 30 days after receipt of the report by the Secretary and the Clerk.

(c) Information that involves intelligence matters shall be reported only to the Select Committee on Intelligence of the Senate, the Permanent Select Committee on Intelligence of the House of Representatives, and the Committees on Appropriations of the Senate and the House of Representatives in accordance with procedures agreed to by such committees. Such information shall not be available for public inspection.

(d) Information that is classified under Executive Order 12356 or any successor order shall be reported only to the Committee on Foreign Relations of the Senate and the Committee on Foreign Affairs of the House of Representatives or the Committees on Armed Services of the Senate and the House of Representatives (whichever such committees have jurisdiction of matters involving such information) and to the Committees on Appropriations of the Senate and the House of Representatives in accordance with procedures agreed to by such committees. Such information shall not be available for public inspection.

(e) The first semi-annual compilation shall be submitted on May 31, 1990, and shall contain a compilation of the disclosure reports received from December 23, 1989 to March 31, 1990.

(f) Major agencies, designated by the Office of Management and Budget (OMB), are required to provide machine-readable compilations to the Secretary of the Senate and the Clerk of the House of Representatives no later than with the compilations due on May 31, 1991. OMB shall provide detailed specifications in a memorandum to these agencies.

(g) Non-major agencies are requested to provide machine-readable compilations to the Secretary of the Senate and the Clerk of the House of Representatives.

(h) Agencies shall keep the originals of all disclosure reports in the official files of the agency.

§ 93.605 Inspector General report.

(a) The Inspector General, or other official as specified in paragraph (b) of this section, of each agency shall prepare and submit to Congress each year, commencing with submission of the President's Budget in 1991, an evaluation of the compliance of that agency with, and the effectiveness of, the requirements herein. The evaluation may include any recommended changes that may be necessary to strengthen or improve the requirements.

(b) In the case of an agency that does not have an Inspector General, the agency official comparable to an Inspector General shall prepare and submit the annual report, or, if there is no such comparable official, the head of the agency shall prepare and submit the annual report.

(c) The annual report shall be submitted at the same time the agency submits its annual budget justifications to Congress.

(d) The annual report shall include the following: All alleged violations relating to the agency's covered Federal actions during the year covered by the report, the actions taken by the head of the agency in the year covered by the report with respect to those alleged violations and alleged violations in previous years, and the amounts of civil penalties imposed by the agency in the year covered by the report.

APPENDIX A TO PART 93—CERTIFICATION REGARDING LOBBYING

Certification for Contracts, Grants, Loans, and Cooperative Agreements

The undersigned certifies, to the best of his or her knowledge and belief, that:

(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Statement for Loan Guarantees and Loan Insurance

The undersigned states, to the best of his or her knowledge and belief, that:

If any funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this commitment providing for the United States to insure or guarantee a loan, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

Submission of this statement is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required statement shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

APPENDIX B TO PART 93—DISCLOSURE FORM TO REPORT LOBBYING

DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB
0348-0046

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

1. Type of Federal Action:
☐
a. contract
b. grant
c. cooperative agreement
d. loan
e. loan guarantee
f. loan insurance

2. Status of Federal Action:
☐
a. bid/offer/application
b. initial award
c. post-award

3. Report Type:
☐
a. initial filing
b. material change

For Material Change Only:
year ______ quarter ______
date of last report ______

4. Name and Address of Reporting Entity:
☐ Prime ☐ Subawardee
Tier ______, *if known:*

Congressional District, *if known:*

5. If Reporting Entity in No. 4 is Subawardee, Enter Name and Address of Prime:

Congressional District, *if known:*

6. Federal Department/Agency:

7. Federal Program Name/Description:

CFDA Number, *if applicable:* ______

8. Federal Action Number, *if known:*

9. Award Amount, *if known:*
$

10. a. Name and Address of Lobbying Entity
(if individual, last name, first name, MI):

b. Individuals Performing Services *(including address if different from No. 10a)*
(last name, first name, MI):

(attach Continuation Sheet(s) SF-LLL-A, if necessary)

11. Amount of Payment *(check all that apply):*
$ ______ ☐ actual ☐ planned

12. Form of Payment *(check all that apply):*
☐ a. cash
☐ b. in-kind; specify: nature ______
value ______

13. Type of Payment *(check all that apply):*
☐ a. retainer
☐ b. one-time fee
☐ c. commission
☐ d. contingent fee
☐ e. deferred
☐ f. other; specify: ______

14. Brief Description of Services Performed or to be Performed and Date(s) of Service, including officer(s), employee(s), or Member(s) contacted, for Payment Indicated in Item 11:

(attach Continuation Sheet(s) SF-LLL-A, if necessary)

15. Continuation Sheet(s) SF-LLL-A attached: ☐ Yes ☐ No

16. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Signature: ______
Print Name: ______
Title: ______
Telephone No.: ______ **Date:** ______

Federal Use Only:

Authorized for Local Reproduction
Standard Form - LLL

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.
2. Identify the status of the covered Federal action.
3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.
4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.
5. If the organization filing the report in item 4 checks "Subawardee", then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.
6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.
7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.
8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."
9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.
10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.

    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).
11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material change report, enter the cumulative amount of payment made or planned to be made.
12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.
13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.
14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.
15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.
16. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

Public reporting burden for this collection of information is estimated to average 30 mintues per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, D.C. 20503.

DISCLOSURE OF LOBBYING ACTIVITIES
CONTINUATION SHEET

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0348-0046

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PART 95—GENERAL ADMINISTRATION—GRANT PROGRAMS (PUBLIC ASSISTANCE AND MEDICAL ASSISTANCE)

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AUTHORITY: Sec. 452(a), 83 Stat. 2351, 42 U.S.C. 652(a); sec. 1102, 49 Stat. 647, 42 U.S.C. 1302; sec. 7(b), 68 Stat. 658, 29 U.S.C. 37(b); sec. 139, 84 Stat. 1323, 42 U.S.C. 2577b; sec. 144, 81 Stat. 529, 42 U.S.C. 2678; sec. 1132, 94 Stat. 530, 42 U.S.C. 1320b-2; sec. 306(b), 94 Stat. 530, 42 U.S.C. 1320b-2 note, unless otherwise noted.

Subpart A—Time Limits for States To File Claims

SOURCE: 46 FR 3529, Jan. 15, 1981, unless otherwise noted.

§ 95.1 Scope.

(a) This subpart establishes a two year time limit (15 months in some cases) for a State to claim Federal financial participation in expenditures under State plans approved under the following titles of the Social Security Act:

Title I—Grants to States for Old-Age Assistance and Medical Assistance for the Aged.

Title IV-A—Grants to States for Aid and Services to Needy Families with Dependent Children (except for Section 402(a)(19)(G) of the Act).

Title IV-B—Child Welfare Services.

Title IV-D—Child Support and Establishment of Paternity.

Title IV-E—Foster Care and Adoption Assistance.

Title X—Grants to States for Aid to the Blind.

Title XIV—Grants to States for Aid to the Permanently and Totally Disabled.

Title XVI—Grants to States for Aid to the Aged, Blind, or Disabled (AABD), or for Such Aid and Medical Assistance for the Aged.

Title XIX—Grants to States for Medical Assistance Programs.

Title XX—Grants to States for Services.

(b) This subpart also applies to claims for Federal financial participation by any State which are based on any provision of the Act that is enacted after issuance of these regulations and that provides, on an entitlement basis, for Federal financial participation in expenditures made under State plans or programs.

(c) This subpart explains under what conditions the Secretary may decide to extend the time limit for filing claims when a State believes it has good cause for not meeting the time limit.

§ 95.4 Definitions.

In this subpart—

Adjustment to prior year costs means an adjustment in the amount of a particular cost item that was previously claimed under an interim rate concept and for which it is later determined that the cost is greater or less than that originally claimed.

Audit exception means a proposed adjustment by the responsible Federal agency to any expenditure claimed by a State by virtue of an audit.

Claim means a request for Federal financial participation in the manner and format required by our program regulations, and instructions or directives issued thereunder.

Court-ordered retroactive payment means either a retroactive payment the State makes to an assistance recipient or an individual, under a Federal or State court order or a retroactive payment we make to a State under a Federal court order. Although we may accept these claims as timely, this provision does not mean that we necessarily agree to be bound by a State or Federal decision when we were not a party to the action.

Federal financial participation means the Federal government's share of an expenditure made by a State agency under any of the programs listed in § 95.1.

State agency for the purposes of expenditures for financial assistance under title IV-A and for support enforcement services under title IV-D means any agency or organization of the State or local government which is authorized to incur matchable expenses; for purposes of expenditures under title XIX, means any agency of the State, including the State Medicaid agency, its fiscal agents, a State health agency, or any other State or local organization which incurs matchable expenses; for purposes of expenditures under all other titles, see the definitions in the appropriate program's regulations.

State means the 50 States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa and the Trust Territories of the Pacific.

The Act means the Social Security Act, as amended.

We, our, and *us* refer to HHS's Health Care Financing Administration, Office of Child Support Enforcement, Office of Human Development Services, or the Social Security Administration, depending on the program involved.

§ 95.7 Time limit for claiming payment for expenditures made after September 30, 1979.

Under the programs listed in § 95.1, we will pay a State for a State agency expenditure made after September 30, 1979, only if the State files a claim with us for that expenditure within 2 years after the calendar quarter in which the State agency made the expenditure. Section 95.19 lists the exceptions to this rule.

§ 95.10 Time limit for claiming payment for expenditures made before October 1, 1979.

Under the programs listed in § 95.1, we will pay a State for a State agency expenditure made before October 1, 1979, only if the State filed or files a claim with us for that expenditure before January 1, 1981. Section 95.19 lists the exceptions to this rule.

§ 95.11 Payment of claims subject to appropriations restrictions.

Notwithstanding any other provision of this Subpart, we will pay States' otherwise allowable claims for Federal financial participation under the programs covered by this Subpart, subject to the availability of funds (as provided in Acts appropriating funds to the Department in effect at the time in which such claims are being considered for payment), and subject to conditions or restrictions applicable to payments out of such funds, including provisions of the first and second continuing resolutions for FY 1981 (Pub. L. 96-369 and Pub. L. 96-536) and the Supplemental Appropriations and Rescission Act, 1981 (Pub. L. 97-12) that make funds under those Acts available to pay for a State agency expenditure made before September 30, 1978, only if the State had filed a claim for that expenditure with us within one year of the expenditure.

(Pub. L. 96-369, 94 Stat. 1351; Pub. L. 96-536, 94 Stat. 3166; and Pub. L. 97-12, 95 Stat. 14)

[46 FR 46136, Sept. 17, 1981]

§ 95.13 In which quarter we consider an expenditure made.

In this subpart—

(a) We consider a State agency's expenditure for assistance payments under title I, IV-A, IV-E, X, XIV, or XVI (AABD) to have been made in the quarter in which a payment was made to the assistance recipient, his or her protective payee, or a vendor payee, even if the payment was for a month in a previous quarter.

(b) We consider a State agency's expenditure for services under title I, IV-A, IV-B, IV-D, IV-E, X, XIV, XVI (AABD) or XIX to have been made in the quarter in which any State agency made a payment to the service provider.

(c) For purposes of title XX, the date of expenditure is governed by 45 CFR 1396.52(d).

(d) We consider a State agency's expenditure for administration or training under title I, IV-A, IV-B, IV-D, IV-E, X, XIV, XVI (AABD), or XIX to have been made in the quarter payment was made by a State agency to a private agency or individual; or in the quarter to which the costs were allocated in accordance with the regulations for each program. We consider a State agency's expenditure under these titles for non-cash expenditures such as depreciation to have been made in the quarter the expenditure was recorded in the accounting records of any State agency in accordance with generally accepted accounting principles.

§ 95.19 Exceptions to time limits.

The time limits in §§ 95.7 and 95.10 do not apply to any of the following—

(a) Any claim for an adjustment to prior year costs.

(b) Any claim resulting from an audit exception.

(c) Any claim resulting from a court-ordered retroactive payment.

(d) Any claim for which the Secretary decides there was good cause for the State's not filing it within the time limit.

§ 95.22 Meaning of good cause.

(a) Good cause for the late filing of a claim is lateness due to circumstances beyond the State's control.

(b) Examples of circumstances beyond the State's control include:

(1) Acts of God;

(2) Documented action or inaction of the Federal government.

(c) Circumstances beyond the State's control do not include neglect or administrative inadequacy on the part of the State, State agencies, the State legislature or any of their offices, officers, or employees.

§ 95.25 When to request a waiver for good cause.

The State should request a waiver in writing as soon as the State recognizes that it will be unable to submit a claim within the appropriate time limit.

§ 95.28 What a waiver request for good cause must include.

The State's request for waiver must include a specific explanation, justifi-

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cation or documentation of why the claim is or will be late. This request must establish that the lateness in filing the claim is for good cause as defined in § 95.22 and not due to neglect or administrative inadequacy. If the claim has not been filed, the State must also tell us when the claim will be filed.

§ 95.31 Where to send a waiver request for good cause.

(a) A request which affects the program(s) of only one HHS agency (the Health Care Financing Administration, or the Office of Child Support Enforcement, or the Office of Human Development Services, or the Social Security Administration) and does not affect the programs of any other agency or Federal Department should be sent to the appropriate HHS agency.

(b) A request which affects programs of more than one HHS agency or Federal Department should be sent to the Director, Division of Cost Allocation in the appropriate HHS Regional Office.

§ 95.34 The decision to waive the time limit for good cause.

The Secretary will make a decision after reviewing the State's request for waiver. If the Secretary decides that good cause exists, the State will be notified of the extended due date. If the Secretary decides that good cause does not exist or that the request for waiver does not provide enough information to make a decision, the State will be so advised.

Subparts B—D [Reserved]

Subpart E—Cost Allocation Plans

SOURCE: 47 FR 17509, Apr. 23, 1982, unless otherwise noted.

§ 95.501 Purpose.

This subpart establishes requirements for:

(a) Preparation, submission, and approval of State agency cost allocation plans for public assistance programs; and

(b) Adherence to approved cost allocation plans in computing claims for Federal financial participation.

§ 95.503 Scope.

This subpart applies to all State agency costs applicable to awards made under Title I, IV-A, IV-B, IV-C, IV-D, IV-E, X, XIV, XVI (AABD), and XIX, of the Social Security Act, and under the Refugee Act of 1980, Title IV, Chapter 2 of the Immigration and Nationality Act (8 U.S.C. 1521 *et seq.*), and under Title V of Pub. L. 96-422, the Refugee Education Assistance Act of 1980.

§ 95.505 Definitions.

As used in this subpart:

"*State agency costs*" include all costs incurred by or allocable to the State agency except expenditures for financial assistance, medical vendor payments, and payments for services and goods provided directly to program recipients such as day care services, family planning services or household items as provided for under the approved State program plan.

"*Cost allocation plan*" means a narrative description of the procedures that the State agency will use in identifying, measuring, and allocating all State agency costs incurred in support of all programs administered or supervised by the State agency.

"*FFP*" or "*Federal financial participation*" means the Federal Government's share of expenditures made by a State agency under any of the programs cited in § 95.503.

"*Operating Divisions*" means The Department of Health and Human Services (HHS) organizational components responsible for administering public assistance programs. These components are the Social Security Administration, Office of Human Development Services, Office of Child Support Enforcement, Health Care Financing Administration, and Office of Refugee Resettlement.

"*Public assistance programs*" means the programs cited in § 95.503.

"*State*" means the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Northern Mariana Islands, and Guam.

"*State agency*" means the State agency administering or supervising the administration of the State plan for any program cited in § 95.503. A

State agency may be an organizational part of a larger State department that also contains other components and agencies. Where that occurs, the expression "*State agency*" refers to the specific component or agency within the State department that is directly responsible for the administration of, or supervising the administration of, one or more programs identified in § 95.503.

"*State Plan*" means a comprehensive written commitment by the State agency to administer or supervise the administration of any of the public assistance programs cited in § 95.503 in accordance with all Federal requirements.

§ 95.507 Cost allocation plan requirements.

(a) The State shall submit a cost allocation plan for the State agency as required below to the Director, Division of Cost Allocation (DCA), in the approporiate HHS Regional Office. The plan shall:

(1) Describe the procedures used to identify, measure, and allocate all costs to each of the programs operated by the State agency;

(2) Conform to the accounting principles and standards prescribed in Office of Management and Budget Circular A-87, and other pertinent Department regulations and instructions;

(3) Be compatible with the State plan for public assistance programs described in 45 CFR Chapters II, III and XIII, and 42 CFR Chapter IV Subchapter C; and

(4) Contain sufficient information in such detail to permit the Director, Division of Cost Allocation, after consulting with the Operating Divisions, to make an informed judgment on the correctness and fairness of the State's procedures for identifying, measuring, and allocating all costs to each of the programs operated by the State agency.

(b) The cost allocation plan shall contain the following information:

(1) An organizational chart showing the placement of each unit whose costs are charged to the programs operated by the State agency.

(2) A listing of all Federal and all non-Federal programs performed, administered, or serviced by these organizational units.

(3) A description of the activities performed by each organizational unit and, where not self-explanatory an explanation of the benefits provided to Federal programs.

(4) The procedures used to identify, measure, and allocate all costs to each benefiting program and activity (including activities subject to different rates of FFP).

(5) The estimated cost impact resulting from the proposed changes to a previously approved plan. These estimated costs are required solely to permit an evaluation of the procedures used for identifying, measuring, and allocating costs. Therefore, approval of the cost allocation plan shall not constitute approval of these estimated costs for use in calculating claims for FFP. Where it is impractical to obtain this data, an alternative approach should then be negotiated with the Director, DCA, prior to submission of the cost allocation plan.

(6) A statement stipulating that wherever costs are claimed for services provided by a governmental agency outside the State agency, that they will be supported by a written agreement that includes, at a minimum (i) the specific service(s) being purchased, (ii) the basis upon which the billing will be made by the provider agency (e.g. time reports, number of homes inspected, etc.) and (iii) a stipulation that the billing will be based on the actual cost incurred. This statement would not be required if the costs involved are specifically addressed in a State-wide cost allocation plan, local-wide cost allocation plan, or an umbrella/department cost allocation plan.

(7) If the public assistance programs are administered by local government agencies under a State supervised system, the overall State agency cost allocation plan shall also include a cost allocation plan for the local agencies. It shall be developed in accordance with the requirements set forth above. More than one local agency plan shall be submitted if the accounting systems or other conditions at the local agencies preclude an equitable allocation of costs by the submission of

a single plan for all local agencies. Prior to submitting multiple plans for local agencies, the State should consult with the Director, DCA. Where more than one local agency plan is submitted, the State shall identify the specific local agencies covered by each plan.

(8) A certification by a duly authorized official of the State stating:

(i) That the information contained in the proposed cost allocation plan was prepared in conformance with Office of Management and Budget Circular A-87.

(ii) That the costs are accorded consistent treatment through the application of generally accepted accounting principles appropriate to the circumstances.

(iii) That an adequate accounting and statistical system exists to support claims that will be made under the cost allocation plan; and

(iv) That the information provided in support of the proposed cost allocation plan is accurate.

(9) Other information as is necessary to establish the validity of the procedures used to identify, measure, and allocate costs to all programs being operated by the State agency.

§ 95.509 Cost allocation plan amendments and certifications.

(a) The State shall promptly amend the cost allocation plan and submit the amended plan to the Director, DCA if any of the following events occur:

(1) The procedures shown in the existing cost allocation plan become outdated because of organizational changes, changes in Federal law or regulations, or significant changes in program levels, affecting the validity of the approved cost allocation procedures.

(2) A material defect is discovered in the cost allocation plan by the Director, DCA or the State.

(3) The State plan for public assistance programs is amended so as to affect the allocation of costs.

(4) Other changes occur which make the allocation basis or procedures in the approval cost allocation plan invalid.

(b) If a State has not submitted a plan or plan amendment during a given State fiscal year, an annual statement shall be submitted to the Director, DCA certifying that its approved cost allocation plan is not outdated. This statement shall be submitted within 60 days after the end of that fiscal year.

§ 95.511 Approval of the cost allocation plan or plan amendment.

(a) The Director, DCA, after consulting with the affected Operating Divisions, shall notify the State in writing of his/her findings. This notification will be made within 60 days after receipt of the proposed plan or amendment and shall either: (1) Advise the State that the plan or plan amendment is approved or disapproved, (2) advise the State of the changes required to make the plan or amendment acceptable, or (3) request the State to provide additional information needed to evaluate the proposed plan or amendment. If the DCA cannot make a determination within the 60-day period, it shall so advise the State.

(b) For purpose of this subpart, State agency cost allocation plans which have been approved by an authorized official of the Department of HHS prior to the effective date of this regulation are considered approved until such time as a new plan or plan amendment is required by § 95.509(a).

§ 95.513 Disapproval of the cost allocation plan or plan amendment.

(a) The Director, DCA, shall notify a State in writing of the disapproval of its cost allocation plan or plan amendment. The notification will set forth the reasons for the determination and the basic changes required in sufficient detail to enable the State to respond and will inform the State of its opportunity for reconsideration of the determination under 45 CFR Part 75.

(b) If the State in accordance with 45 CFR Part 75, wishes to request a reconsideration of the DCA's determination, the application for reconsideration must be postmarked no later than 30 days after receipt of the DCA's determination letter.

§ 95.515 Effective date of a cost allocation plan amendment.

As a general rule, the effective date of a cost allocation plan amendment shall be the first day of the calendar quarter following the date of the event that required the amendment (See § 95.509). However, the effective date of the amendment may be earlier or later under the following conditions:

(a) An earlier date is needed to avoid a significant inequity to either the State or the Federal Government.

(b) The information provided by the State which was used to approve a previous plan or plan amendment is later found to be materially incomplete or inaccurate, or the previously approved plan is later found to violate a Federal statute or regulation. In either situation, the effective date of any required modification to the plan will be the same as the effective date of the plan or plan amendment that contained the defect.

(c) It is impractical for the State to implement the amendment on the first day of the next calendar quarter. In these instances, a later date may be established by agreement between the State and the DCA.

§ 95.517 Claims for Federal financial participation.

(a) A State must claim FFP for costs associated with a program only in accordance with its approved cost allocation plan. However, if a State has submitted a plan or plan amendment for a State agency, it may, at its option claim FFP based on the proposed plan or plan amendment, unless otherwise advised by the DCA. However, where a State has claimed costs based on a proposed plan or plan amendment the State, if necessary, shall retroactively adjust its claims in accordance with the plan or amendment as subsequently approved by the Director, DCA. The State may also continue to claim FFP under its existing approved cost allocation plan for all costs not affected by the proposed amendment.

§ 95.519 Cost disallowance.

If costs under a Public Assistance program are not claimed in accordance with the approved cost allocation plan (except as otherwise provided in § 95.517), or if the State failed to submit an amended cost allocation plan as required by § 95.509, the costs improperly claimed will be disallowed.

(a)(1) If the issue affects the program(s) of only one Operating Division and does not affect the programs of other Operating Divisions or Federal departments, that Operating Division will determine the amount of the disallowance and will also inform the State of its opportunity for reconsideration of the determination in accordance with the Operating Division's procedures. Prior to issuing the notification, however, the Operating Division shall consult with the DCA to ensure that the issue does not affect the programs of other Operating Divisions or Federal departments.

(2) If the State wishes to request a reconsideration of the Operating Division's determination, it must submit the request in accordance with the Operating Division's procedures.

(b)(1) If the issue affects the programs of more than one Operating Division, or Federal department or the State, the Director, DCA, after consulting with the Operating Divisions, shall determine the amount inappropriately claimed under each program. The Director, DCA will notify the State of this determination, of the dollar affect of the determination on the claims made under each program, and will inform the State of its opportunity for reconsideration of the determination under 45 CFR Part 75. The State will subsequently be notified by the appropriate Operating Division as to the disposition of the funds in question.

(2) If the State, in accordance with 45 CFR Part 75, wishes to request a reconsideration of the DCA's determination, the application for reconsideration must be postmarked no later than 30 days after receipt of the DCA's determination letter. In considering an appeal under this process, the Regional Director shall consult with HHS Operating and staff Divisions as appropriate.

Subpart F—Automatic Data Processing Equipment and Services—Conditions for Federal Financial Participation (FFP)

AUTHORITY: Secs. 402(a)(5), 452(a)(1), 1102 and 1902(a)(4) of the Social Security Act, 42 U.S.C. 602(a)(5), 652(a)(1), 1302, 1396a(a)(4); 5 U.S.C. 301 and 8 U.S.C. 1521.

SOURCE: 51 FR 45326, Dec. 18, 1986, unless otherwise noted.

GENERAL

§ 95.601 Scope and applicability.

This subpart prescribes part of the conditions under which the Department of Health and Human Services will approve Federal financial participation (FFP) at the applicable rates for the costs of automatic data processing incurred under an approved State plan for titles I, IV-A, IV-B, IV-D, IV-E, X, XIV, XVI(AABD), or XIX of the Social Security Act and title IV chapter 2 of the Immigration and Nationality Act. The conditions of approval of this subpart add to the statutory and regulatory requirements for acquisition of ADP equipment and services under the specified titles of the Social Security Act.

(Approved by the Office of Management and Budget under control number 0990-0174)

[55 FR 4375, Feb. 7, 1990]

DEFINITIONS

§ 95.605 Definitions.

As used in this part, the term:

"Acceptance documents" means written evidence of satisfactory completion of an approved phase of work or contract, and acceptance thereof by the State agency.

"Acquisition" means acquiring ADP equipment or services from commercial sources or from State or local government resources.

Advance Planning Document ("APD"), "Initial advance automatic data processing planning document" or "Initial APD" means a written plan of action to request funding approval for a project which will require the use of ADP services or equipment. The term "APD" refers to a "Planning APD", or to a planning and/or, development and implementation action document, i.e., "Implementation APD", or to an "Advance Planning Document Update".

(1) *Planning APD* means a written plan of action which requests FFP to determine the need for, feasibility, and cost factors of an APD equipment or services acquisition and to perform one or more of the following: Prepare a "Functional Requirements Specification"; assess other States' systems for transfer, to the maximum extent possible, of an existing system; prepare an "Implementation APD"; prepare a request for proposal (RFP) or develop a General Systems Design (GSD).

A separate planning effort and "Planning APD" is generally applicable to large enhanced funded Statewide system developments and/or major hardware acquisitions. States with large, independent Counties requesting funding at the regular match rate for County systems are strongly encouraged to do better planning and to submit a "Planning APD" to allow for time and to provide funding for its planning activities. Therefore, states must consider the scope and complexity of a project to determine whether to submit a "Planning APD" as a separate document to HHS or whether to combine the two phases of planning and implementation into one APD covering both the "Planning APD" and the "Implementation APD" requirements.

The *Planning APD* is a relatively brief document, usually not more than 6-10 pages, which must contain:

(i) A statement of the problem/need in terms of deficiencies in existing capabilities, new or changed program requirements or opportunities for economies and efficiencies;

(ii) A project management plan which addresses the planning project organization, planning activities/deliverables, State and contractor resource needs, planning project procurement activities and schedule;

(iii) A specific budget for the planning of the project;

(iv) An estimated total project cost and a prospective State and Federal cost distribution, including planning and implementation;

(v) A commitment to conduct/prepare the needs assessment, feasibility study, alternatives analysis, cost benefit analysis, and to develop a Functional Requirements Specification and/or a General Systems Design (GSD); and,

(vi) A commitment to define the State's functional requirements for the purpose of evaluating the transfer of an existing system, including the transfer of another State's General System Design, which the State may adapt to meet State specific requirements.

Additional *Planning APD* content requirements, for enhanced funding projects are contained in 45 CFR 205.37(a)(1)-(8) and CFR 307.15.

(2) *Implementation APD* means a written plan of action to acquire the proposed APD services or equipment.

The *Implementation APD* shall include:

(i) The results of the activities conducted under a Planning APD, if any;

(ii) A statement of needs and objectives;

(iii) A requirements analysis, feasibility study and a statement of alternative considerations including, where appropriate, a transfer of an existing system and an explanation of why such a transfer is not feasible if another alternative is identified;

(iv) A cost benefit analysis;

(v) A personnel resource statement indicating availability of qualified and adequate staff, including a project director to accomplish the project objectives;

(vi) A detailed description of the nature and scope of the activities to be undertaken and the methods to be used to accomplish the project;

(vii) The proposed activity schedule for the project;

(viii) A proposed budget (including a consideration of all possible "Implementation APD" activity costs, e.g., system conversion, computer capacity planning, supplies, training, and miscellaneous ADP expenses) for the project;

(ix) A statement indicating the period of time the State expects to use the equipment or system;

(x) An estimate of prospective cost distribution to the various State and Federal funding sources and the proposed procedures for distributing costs; and

(xi) A statement setting forth the security and interface requirements to be employed and the system failure and disaster recovery procedures available.

Additional requirements, for acquisitions for which the State is requesting enhanced funding, are contained at 45 CFR 205.37(a)(1)-(8), 45 CFR 307.15 and 42 CFR part 433 subpart C.

(3) *Advance Planning Document Update* (APDU) means a document submitted "annually" (Annual APDU) to report project status and/or post implementation cost-savings, or on an "as needed" (As Needed APDU) basis to request funding approval for project continuation when significant project changes are anticipated; for incremental funding authority and project continuation when approval is being granted by phase; or to provide detailed information on project and/or budget activities.

(a) The *Annual APDU* is due 60 days from the *Planning APD* or "Implementation APD" approved anniversary and includes:

(i) A reference to the approved APD and all approved changes;

(ii) A project activity status which reports the status of the past year's major project tasks and milestones, addressing the degree of completion and tasks/milestones remaining to be completed and discusses past and anticipated problems or delays in meeting target dates in the approved APD and approved changes to it;

(iii) A report of all project deliverables completed in the past year and degree of completion for unfinished products;

(iv) A project activity schedule for the remainder of the project;

(v) A project expenditures status which consists of a detailed accounting of all expenditures for project development over the past year and an explanation of the differences between projected expenses in the approved APD and actual expenditures for the past year;

(vi) A report of any approved or anticipated changes to the allocation basis in the APD's approved cost methodology;

(vii) A report which compares the estimated cost-savings from the State's approved APD to actual cost-benefits to date (in the development phase of a project, this may be reported as non-applicable). The proportion of costs to savings must remain as projected in the APD. Once the State begins operation, either on a pilot basis or under a phased approval, the cost-savings shall be submitted 2-5 years after statewide operation until the Department determines projected cost savings have been achieved.

(b) The "As Needed APDU" is defined as a document which requests approval for additional funding and/or authority for project continuation when significant changes are anticipated; when the project is being funded on a phased implementation basis; to clarify project information requested as an approval condition of the "Planning APD" or "Implementation APD". The "As Needed APDU" may be submitted anytime as a stand-alone funding or project continuation request, or may be submitted with the "Annual APDU":

(i) When the State anticipates incremental project expenditures (exceeding specified thresholds);

(ii) When the State anticipates a schedule extension of more than 60 days for major milestones. For Aid to Families with Dependent Children (AFDC) Family Assistance Management Information System (FAMIS)-type projects, in accordance with section 402(e)(2)(C) of the Social Security Act, any schedule change which affects the State's implementation date as specified in the approved APD requires that the Department recover 40 percent of the amount expended. The Secretary may extend the implementation date, if the implementation date is not met because of circumstances beyond the State's control. Examples of circumstances beyond the State's control are:

(*1*) Equipment failure due to physical damage or destruction; or,

(*2*) Change imposed by Federal judicial decisions, or by Federal legislation or regulations;

(iii) When the State anticipates major changes in the scope of its project, e.g., a change in its procurement plan, procurement activities, system concept or development approach;

(iv) When the State anticipates significant changes to its cost distribution methodology or distribution of costs among Federal programs; and/or,

(v) When the State anticipates significant changes to its cost-benefit projections.

The "As needed APDU" shall provide supporting documentation to justify the need for a change to the approved budget.

"Approving component" means an organization within the Department that is authorized to approve requests for the acquisition of ADP equipment or ADP services. Family Support Administration (FAS) for cash assistance for Titles I, IV-A, X, XIV, and XVI(AABD); Office of Human Development Services (OHDS) for social services for Titles IV-B (child welfare services) and IV-E (foster care and adoption assistance); Family Support Administration (FSA) for Title IV-D; and Health Care Financing Administration (HCFA) for Title XIX of the Social Security Act.

"Automatic data processing" or "ADP" means data processing performed by a system of electronic or electrical machines so interconnected and interacting as to minimize the need for human assistance or intervention.

"Automatic data processing equipment" or "ADP equipment" or "Hardware" means automatic equipment that accepts and stores data, performs calculations and other processing steps, and produces information. This includes:

(a) Electronic digital computers;

(b) Peripheral or auxiliary equipment used in support of electronic computers;

(c) Data transmission or communications equipment, and

(d) Data input equipment.

Automatic Data Processing Services or ADP Services means:

(a) Services to operate ADP equipment, either by agency, or by State or local organizations other than the State agency; and/or

(b) Services provided by private sources or by employees of the State agency or by State and local organizations other than the State agency to perform such tasks as feasibility studies, system studies, system design efforts, development of system specifications, system analysis, programming, system conversion and system implementation and include, for example, the following:

(1) Systems Training,

(2) Systems Development,

(3) Site Preparation,

(4) Data Entry, and

(5) Personal services related to automated systems development and operations that are specifically identified as part of a "Planning ADP" or "Implementation ADP". As an example, a personal service would be the service of an "expert individual" to provide advice on the use of ADP software or hardware in developing a State automated management information system.

"Data processing" means the preparation of source media containing data or basic elements of information and the use of such source media according to precise rules or procedures to accomplish such operations as classifying, sorting, calculating, summarizing, recording and transmitting.

"Department" means the Department of Health and Human Service.

"Design" or "system design" means a combination of narrative and diagrams describing the structure of a new or more efficient automatic data processing system. This includes the use of hardware to the extent necessary for the design phase.

"Development" means the definition of system requirements, detailing of system and program specifications, programming and testing. This includes the use of hardware to the extent necessary for the development phase.

"Emergency situation" is defined as a situation where:

(a) A State can demonstrate to the Department an immediate need to acquire ADP equipment or services in order to continue the operation of one or more of the Social Security Act programs covered by Subpart F, and

(b) The State can clearly document that the need could not have been anticipated or planned for and the State was prevented from following the prior approval requirements of § 95.611.

"Enhanced matching rate" means the higher than regular rate of FFP authorized by Title IV-A, IV-D, and XIX of the Social Security Act for acquisition of services and equipment that conform to specific requirements designed to improve administration of the Aid to Families with Dependent Children, Child Support Enforcement and Medicaid programs.

"Enhancement" means modifications which change the functions of software and hardware beyond their original purposes, not just to correct errors or deficiencies which may have been present in the software or hardware, or to improve the operational performance of the software or hardware.

"Feasibility study" means a preliminary study to determine whether it is sufficiently probable that effective and efficient use of ADP equipment or systems can be made to warrant a substantial investment of staff, time, and money being requested and whether the plan is capable of being accomplished successfully.

"FFP" means Federal financial participation.

Functional Requirements Specification is defined as an initial definition of the proposed system, which documents the goals, objectives, user or programmatic requirements, management requirements, the operating environment, and the proposed design methodology, e.g., centralized or distributed. This document details what the new system and or hardware should do, not how it is to do it. The Specifications document shall be based upon a clear and accurate description of the functional requirements for the project, and shall not, in competitive procurements, lead to requirements which unduly restrict competition. The Specification document is the user's definition of the requirements the system must meet.

General Systems Design means a combination of narrative and graphic description of the generic architecture of a system as opposed to the detailed architecture of the system. A general systems design would include a systems diagram and narrative identifying overall logic flow and systems functions; a description of equipment needed (including processing data transmission and storage requirements); a description of other resource requirements which will be necessary to operate the system; a description of system performance requirements; and a description of the physical and organizational environment in which the system will operate including how the system will function within that environment (e.g. how workers will interface with the system).

Project means an automated systems effort undertaken by the State to improve the administration and/or operation of one or more of its public assistance programs. For example, a State may undertake a comprehensive, integrated initiative in support of its AFDC and Medicaid programs' intake, eligibility and case management functions. A project may also be a less comprehensive activity such as, office automation, enhancements to an existing system or an upgrade of computer hardware.

Implementation means design, development and installation and does not include operation.

Medicaid Management Information System (MMIS) is a commonly accepted term for "Mechanized Claim Processing and Information Retrieval System" as provided by Section 1903(a)(3) and 1903(r) of the Social Security Act and at 42 CFR 433.110 et seq.

Total Acquisition Cost means all anticipated expenditures (including State staff costs) for planning and implementation for the project. For purposes of this regulation total acquisition cost and project cost are synonymous.

"Installation" means the integrated testing of programs and subsystems, system conversion, and turnover to operation status. This includes the use of hardware to the extent necessary for the installation phase.

"Operation" means the automated processing of data used in the administration of State plans for Title I, IV-A, IV-B, IV-D, IV-E, X, XIV, XVI(AABD) of XIX of the Social Security Act. Operation includes the use of supplies, software, hardware, and personnel directly associated with the functioning of the mechanized system. See 45 CFR 205.38 and 307.10 for specific requirements for Title IV-A and IV-D, and 42 CFR 433.112 and 42 CFR 433.113 for specific requirements for Title XIX.

"Regular matching rate" means the normal rate of FFP authorized by Titles IV-A, IV-B, IV-D, IV-E, X, XIV, XVI(AABD) and XIX of the Social Security Act of State and local agency administration of programs authorized by those titles.

"Requirements Analysis" means determining and documenting the information needs and the functional and technical requirements the proposed computerized system must meet.

"Service agreement" means the document signed by the State or local agency and the State or local Central Data Processing facility whenever the latter provides data processing services to the former and:

(a) Identifies those ADP services the Central Data Processing facility will provide;

(b) Includes, preferably as an amendable attachment, a schedule of charges for each identified ADP service, and a certification that these charges apply equally to all users;

(c) Includes a description of the method(s) of accounting for the services rendered under the agreement and computing services charges.

(d) Includes assurances that services provided will be timely and satisfactory;

(e) Includes assurances that information in the computer system as well as access, use and disposal of ADP data will be safeguarded in accordance with provisions of 45 CFR 205.50 and 303.21;

(f) Requires the provider to obtain prior approval pursuant to 45 CFR 95.611(a) from the Department for ADP equipment and ADP services that are acquired from commercial sources primarily to support the titles covered by this subpart and requires the provider to comply with 45 CFR Part 74, Subpart P for procurements related to the service agreement. ADP equipment and services are considered to be primarily acquired to support the titles covered by this subpart when these titles may reasonably be expected to either: Be billed for more than 50 percent of the total charges made to all users of the ADP equipment and services during the time period covered by the service agreement, or directly charged for the total cost of the purchase or lease of ADP equipment or services;

(g) Includes the beginning and ending dates of the period of time covered by the service agreement; and

(h) Includes a schedule of expected total charges to the title covered by this subpart for the period of the service agreement.

"Software" means a set of computer programs, procedures, and associated documentation used to operate the hardware.

"State agency" means the State agency administering or supervising the administration of the State plan under Titles I, IV, X, XIV, XVI (AABD) or XIX of the Social Security Act.

"System specifications" means information about the new ADP system—such as workload descriptions, input data, information to be maintained and processed, data processing techniques, and output data—which is required to determine the ADP equipment and software necessary to implement the system design.

"System study" means the examination of existing information flow and operational procedures within an organization. The study essentially consists of three basic phases: Data gathering investigation of the present system and new information requirements; analysis of the data gathered in the investigation; and synthesis, or refitting of the parts and relationships uncovered through the analysis into an efficient system.

[51 FR 45326, Dec. 18, 1986, as amended at 55 FR 4375, Feb. 7, 1990]

§ 95.611 Specific Conditions for FFP.

(a) *General acquisition requirements.*—(1) A State shall obtain prior written approval from the Department as specified in paragraph (b) of this section, when the State plans to acquire ADP equipment or services with proposed FFP at the regular matching rate that it anticipates will have total acquisition costs of $500,000 or more in Federal and State funds.

(2) A State shall obtain prior written approval from the Department as specified in paragraph (b) of this section, when the State plans to acquire ADP equipment or services with proposed FFP at the enhanced matching rate authorized by 45 CFR 205.35, 45 CFR part 307 or 42 CFR part 433, subpart C, regardless of the acquisition cost, except as specified in paragraph (a)(3) of this section.

(3) A State shall obtain prior written approval, when the State plans to acquire ADP equipment or services in support of the operation of the approved State Medicaid System, when it anticipates the total acquisition costs will be $500,000 or more in Federal and State funds and the State plans to claim FFP at the 75 percent rate for the ADP equipment or services to be acquired.

(4) A State shall obtain prior written approval from the Department as specified in paragraph (b) of this section, when it plans to acquire noncompetitively from a nongovernmental source ADP equipment or services, with proposed FFP at the regular matching rate, that has a total acquisition cost of more than $100,000.

(5) Except as provided for in paragraph (a)(6) of this section, the State shall submit requests for Department approval, signed by the appropriate State official, to the Associate Administrator, Family Support Administration, Office of Management and Information Systems. The State shall send to FSA one copy of the request for each HHS component, from which the State is requesting funding, and one for the State Data Systems Staff, the coordinating staff for these requests. The State must also send one copy of the request directly to each Regional

program component and one copy to the Regional Director.

(6) States shall submit requests for approval which involve solely Title XIX funding (i.e., State Medicaid Systems), to HCFA for action.

(7) The Department will not approve any Planning or Implementation ADP that does not include all information required as defined in § 95.605.

(b) *Specific prior approval requirements.* The State agency shall obtain written approval of the Department prior to the initiation of project activity.

(1) For regular FFP requests.

(i) For the Planning APD subject to the dollar thresholds specified in paragraph (a) of this section.

(ii) For the Implementation APD subject to the dollar thresholds specified in paragraph (a) of this section.

(iii) For the Request for Proposal and Contract, unless specifically exempted by the Department, prior to release of the RFP or prior to the execution of the contract when the contract is anticipated to or will exceed $300,000.

(iv) For contract amendments, unless specifically exempted by the Department, prior to execution of the contract amendment involving contract cost increases exceeding $100,000 or contract time extensions of more than 60 days.

(2) For enhanced FFP requests.

(i) For the Planning APD.

(ii) For the Implementation APD.

(iii) For the Request for Proposal and contract, unless specifically exempted by the Department, prior to release of the RFP or prior to execution of the contract when the contract is anticipated to or will exceed $100,000.

(iv) For contract amendments, unless specifically exempted by the Department, prior to execution of the contract amendment, involving contract cost increases exceeding $100,000 or contract time extensions of more than 60 days.

(3) Failure to submit any of the above to the satisfaction of the Department may result in disapproval or suspension of project funding. ⊖

(c) *Specific approval requirements.* The State agency shall obtain written approval from the Department:

(1) For regular FFP requests.

(i) For an Annual APDU for projects with a total acquisition of more than one million dollars, when specifically required by the Department.

(ii) For an "As Needed APDU" when changes cause any of the following:

(A) A projected cost increase of $300,000 or 10 percent of the project cost, whichever is less;

(B) A schedule extension of more than 60 days for major milestones;

(C) A significant change in procurement approach, and/or scope of procurement activities beyond that approved in the APD;

(D) A change in system concept, or a change to the scope of the project;

(E) A change to the approved cost allocation methodology.

The State shall submit the "As Needed APDU" to the Department, no later than 60 days after the occurrence of the project changes to be reported in the "As Needed APDU".

(2) For enhanced FFP requests.

(i) For an Annual APDU.

(ii) For an "As needed" APDU when changes cause any of the following:

(A) A projected cost increase of $100,000 or 10 percent of the project cost, whichever is less;

(B) A schedule extension of more than 60 days for major milestones. For Aid to Families with Dependent Children (AFDC) Family Assistance Management Information System (FAMIS)-type projects, in accordance with section 402(e)(2)(C) of the Social Security Act, any schedule change which affects the State's implementation date as specified in the approved APD requires that the Department recover 40 percent of the amount expended. The Secretary may extend the implementation date, if the implementation date is not met because of circumstances beyond the State's control. Examples of circumstances beyond the State's control are:

(1) Equipment failure due to physical damage or destruction; or,

(2) Change imposed by Federal judicial decisions, or by Federal legislation or regulations;

(C) A significant change in procurement approach, and/or a scope of procurement activities beyond that approved in the APD;

(D) A change in system concept or scope of the project;

(E) A change to the approved cost methodology;

(F) A change of more than 10% of estimated cost benefits.

The State shall submit the "As Needed APDU" to the Department, no later than 60 days after the occurrence of the project changes to be reported in the "As Needed APDU".

(3) Failure to submit any of the above to the satisfaction of the Department may result in disapproval or suspension of project funding.

(d) *Prompt action or requests for prior approving.* The ASMB will promptly send to the approving components the items specified in paragraph (b) of this section. If the Department has not communicated approval or disapproval within 30 days the ASMB or an approving component will notify the State regarding the status of the request.

[51 FR 45326, Dec. 18, 1986, as amended at 55 FR 4377, Feb. 7, 1990]

§ 95.612 Disallowance of Federal Financial Participation (FFP).

If the Department finds that any ADP acquisition approved or modified under the provisions of § 95.611 fails to comply with the criteria, requirements, and other undertakings described in the approved advance planning document to the detriment of the proper and efficient operation of the affected program, payment of FFP may be disallowed. In the case of a suspension of approval of an APD for enhanced funding, see 45 CFR 205.37(c), 307.40(a) and 307.35(d).

[55 FR 4378, Feb. 7, 1990]

§ 95.613 Procurement standards.

(a) Procurements of ADP equipment and services are subject to the procurement standards prescribed by Subpart P of 45 CFR Part 74 regardless of any conditions for prior approval. Those standards include a requirement for maximum practical open and free competition regardless of whether the procurement is formally advertised or negotiated.

(b) Those standards, as well as the requirement for prior approval, apply to ADP services and equipment acquired by a State or local agency, and the ADP services and equipment acquired by a State or local Central Data Processing facility primarily to support the Social Security Act programs covered by this subpart. Service agreements are exempt from these procurement standards.

§ 95.615 Access to systems and records.

In accordance with 45 CFR Part 74, the State agency must allow the Department access to the system in all of its aspects, including design developments, operation, and cost records of contractors and subcontractors at such intervals as are deemed necessary by the Department to determine whether the conditions for approval are being met and to determine the efficiency, economy and effectiveness of the system.

[43 FR 44853, Sept. 29, 1978, as amended at 45 FR 10794, Feb. 19, 1980]

§ 95.617 Software and ownership rights.

(a) *General.* The State or local government must include a clause in all procurement instruments that provides that the State or local government will have all ownership rights in software or modifications thereof and associated documentation designed, developed or installed with Federal financial participation under this subpart.

(b) *Federal license.* The Department reserves a royalty-free, nonexclusive, and irrevocable license to reproduce, publish, or otherwise use and to authorize others to use for Federal Government purposes, such software, modifications, and documentation.

(c) *Proprietary software.* Proprietary operating/vendor software packages (e.g., ADABAS or TOTAL) which are provided at established catalog or market prices and sold or leased to the general public shall not be subject to the ownership provisions in paragraphs (a) and (b) of this section. FFP is not available for proprietary applications software developed specifically for the public assistance programs covered under this subpart.

§ 95.619 Use of ADP systems.

ADP systems designed, developed, or installed with FFP shall be used for a period of time specified in the advance planning document, unless the Department determines that a shorter period is justified.

§ 95.621 ADP reviews.

The Department will conduct periodic onsite surveys and reviews of State and local agency ADP methods and practices to determine the adequacy of such methods and practices and to assure that ADP equipment and services are utilized for the purposes consistent with proper and efficient administration under the Act. Where practical, the Department will develop a mutually acceptable schedule between the Department and State or local agencies prior to conducting such surveys or reviews, which may include but are not limited to:

(a) *Pre-installation readiness.* A pre-installation survey including an onsite evaluation of the physical site and the agency's readiness to productively use the proposed ADP services, equipment or system when installed and operational.

(b) *Post-installation.* A review conducted after installation of ADP equipment or systems to assure that the objectives for which FFP was approved are being accomplished.

(c) *Utilization.* A continuing review of ADP facilities to determine whether or not the ADP equipment or services are being efficiently utilized in support of approved programs or projects.

(d) *Acquisitions not subject to prior approval.* Reviews will be conducted on an audit basis to assure that system and equipment acquisitions costing less the $200,000 were made in accordance with 45 CFR Part 74 and the conditions of this subpart and to determine the efficiency, economy and effectiveness of the equipment or system.

(e) *State Agency Maintenance of Service Agreements.* (1) The State agency will maintain a copy of each service agreement in its files for Federal review.

(2) A State agency that did not obtain prior approval of a service agreement, as required by § 95.611(b)(2) as it was in effect from December 28, 1978 (unless a State chose to exercise the option to make it effective as early as September 29, 1978) through January 19, 1987, is eligible for FFP claimed for services furnished by other State or local agencies under that agreement if:

(i) The State agency has a copy of it in its files for Federal review;

(ii) It meets the definition of a service agreement as it was defined in section 95.605 from December 28, 1978 through January 19, 1987;

(iii) The claim conforms to the timely claim provisions of 45 CFR Part 95, Subpart A; and

(iv) The service agreement was not previously disapproved by HHS.

(f) *ADP System Security Requirements and Review Process*—(1) *ADP System Security Requirement.* State agencies are responsible for the security of all ADP projects under development, and operational systems involved in the administration of HHS programs. State agencies shall determine the appropriate ADP security requirements based on recognized industry standards or standards governing security of Federal ADP systems and information processing.

(2) *ADP Security Program.* State ADP Security requirements shall include the following components:

(i) Determination and implementation of appropriate security requirements assecified in paragraph (f)(1) of this section.

(ii) Establishment of a security plan and, as appropriate, policies and procedures to address the following area of ADP security:

(A) Physical security of ADP resources;

(B) Equipment security to protect equipment from theft and unauthorized use;

(C) Software and data security;

(D) Telecommunications security;

(E) Personnel security;

(F) Contingency plans to meet critical processing needs in the event of short or long-term interruption of service;

(G) Emergency preparedness; and,

(H) Designation of an Agency ADP Security Manager.

(iii) Periodic risk analyses. State agencies must establish and maintain a program for conducting periodic risk analyses to ensure that appropriate, cost effective safeguards are incorporated into new and existing systems. State agencies must perform risk analyses whenever significant system changes occur.

(3) *ADP System Security Reviews.* State agencies shall review the ADP system security of installations involved in the administration of HHS programs on a biennial basis. At a minimum, the reviews shall include an evaluation of physical and data security operating procedures, and personnel practices.

(4) Costs incurred in complying with provisions of paragraphs (f)(1)-(3) of this section are considered regular administrative costs which are funded at the regular match rate.

(5) The security requirements of this section apply to all ADP systems used by State and local governments to administer programs covered under 45 CFR part 95, subpart F.

(6) Heads of State agencies after completing the required biennial ADP system security review, shall provide the Department with a written summary of the State's findings and determination of compliance with these ADP security requirements. The State shall describe its ADP security program and prepare an action plan with scheduled dates of milestones which when completed will correct any security weaknesses. The State shall certify compliance with those areas cited in paragraph (f)(2) of this section.

[43 FR 44853, Sept. 29, 1978, as amended at 51 FR 45329, Dec. 18, 1986; 53 FR 27, Jan. 4, 1988; 55 FR 4378, Feb. 7, 1990]

§ 95.623 Waiver of prior approval requirements.

For ADP equipment and services acquired by a State without prior written approval, the Department may waive the prior approval requirement if prior to December 1, 1985:

(a) The State submitted to the Department all information required under § 95.611, satisfactorily responded to all concerns raised by the Department and received a final letter of approval from the Department; or,

(b) The State has a request pending with the Department for retroactive approval, which the Department received before December 1, 1985 and the Department determines that the request would have received prior approval had a timely request for such approval been made by the State agency.

[51 FR 3339, Jan. 27, 1986, as amended at 55 FR 4378, Feb. 7, 1990]

§ 95.624 Consideration for FFP in emergency situations.

For ADP equipment and services acquired by a State after December 1, 1985 to meet emergency situations, which preclude the State from following the requirements of § 95.611, the Department will consider providing FFP upon receipt of a written request from the State. In order for the Department to consider providing FFP in emergency situations, the following conditions must be met:

(a) The State must submit a written request to the Department, prior to the acquisition of any ADP equipment or services. The written request must be sent by registered mail and include:

(1) A brief description of the ADP equipment and/or services to be acquired and an estimate of their costs;

(2) A brief description of the circumstances which result in the State's need to proceed prior to obtaining approval from the Department; and

(3) A description of the harm which will be caused if the State does not acquire immediately the ADP equipment and services.

(b) Upon receipt of the information, the Department will within 14 days take one of the following actions:

(1) Inform the State in writing that the request has been disapproved and the reason for disapproval; or

(2) Inform the State in writing that the Department recognizes that an emergency exists and that within 90 days from the date of the State's initial written request, the State must submit a formal request for approval which includes the information specified at § 95.611 in order for the ADP equipment or services acquisition to be

considered for the Department's approval.

(c) If the Department approves the request submitted under paragraph (b) of this section, FFP will be available from the date the State acquires the ADP equipment and services.

[51 FR 3339, Jan. 27, 1986, as amended at 55 FR 4378, Feb. 7, 1990]

§ 95.625 Increased FFP for certain ADP systems.

(a) *General.* FFP is available at enhanced matching rates for the development of individual or integrated systems and the associated computer equipment that support the administration of State plans for Titles IV–A, IV–D and/or XIX provided the systems meet the specifically applicable provisions referenced in paragraph (b) of the section.

(b) *Specific reference to other regulations.* The applicable regulations for the Title IV–A program are contained in 45 CFR 205.35. The applicable regulations for the Title IV–D program are contained in 45 CFR Part 307. The applicable regulations for the Title XIX program are contained in 45 CFR Part 433, Subpart C.

FEDERAL FINANCIAL PARTICIPATION IN COSTS OF ADP ACQUISITIONS

§ 95.631 Cost identification for purposes of FFP claims.

The conditions of this subpart apply notwithstanding the existence of an approved cost allocation plan. State agencies shall assign and claim the costs incurred under an approved APD in accordance with the following criteria:

(a) *Development costs.* (1) Using its normal departmental accounting system, the State agency shall specifically identify what items of costs constitute development costs, assign these costs to specific project cost centers, and distribute these costs to funding sources based on the specific identification, assignment and distribution outlined in the approved APD; (2) the methods for distributing costs set forth in the APD should provide for assigning identifiable costs, to the extent practicable, directly to program/functions. The State agency shall amend the cost allocation plan required by Subpart E of this part to include the approved APD methodology for the identification, assignment and distribution of the development costs.

(b) *Operational costs.* Costs incurred for the operation of an ADP system shall be identified and assigned by the State agency to funding sources in accordance with the approved cost allocation plan required by Subpart E of this part.

(c) *Service agreement costs.* States that operate a central data processing facility shall use their approved central service cost allocation plan required by OMB Circular A–87 to identify and assign costs incurred under service agreements with the State agency. The State agency will then distribute these costs to funding sources in accordance with paragraphs (a) and (b) of this section.

§ 95.633 Nondiscrimination requirements.

State agencies that acquire ADP equipment and services are subject to the nondiscrimination requirements in Parts 80, 84, and 90.

[45 FR 10794, Feb. 19, 1980]

EXEMPTIONS

§ 95.641 Applicability of rules for charging equipment in Subpart G of this part.

ADP equipment, as well as other equipment acquired under public assistance programs, is subject to Subpart G of this part. Among other things, Subpart G provides that a State may charge only depreciation or use allowances for equipment with unit acquisition cost of over $25,000. However, for ADP equipment HHS will consider requests for waivers of that restriction. If the acquisition of the equipment is part of an APD that is subject to the prior approval requirements of Subpart F, the State may submit the request for a waiver as part of the APD.

Subpart G—Equipment Acquired Under Public Assistance Programs

SOURCE: 47 FR 41576, Sept. 21, 1982, unless otherwise noted.

§ 95.701 Purpose and scope of subpart.

(a) This subpart prescribes requirements concerning the computation of claims for Federal financial participation in the cost of equipment under public assistance programs. This subpart also prescribes requirements for the management and disposition of equipment whose costs are claimed for Federal financial participation under these programs.

(b) This subpart applies to equipment purchased by State agencies (as defined in § 95.703) and to equipment purchased under service agreements with other State agencies and under cost-type contracts.

§ 95.703 Definitions.

As used in this subpart:

"*Acquisition cost*" of an item of purchased equipment means the net invoice price of the equipment, including the cost of modifications, attachments, accessories, or auxiliary apparatus necessary to make the equipment usable for the purpose for which it was acquired. Other charges such as the cost of installation, transportation, taxes, duty or protective intransit insurance shall be included in or excluded from the unit acquisition cost in accordance with the regular accounting practices of the organization purchasing the equipment. If the item is acquired by trading in another item and paying an additional amount, "*acquisition cost*" means the amount received for trade-in plus the additional outlay.

"*Equipment*" means an article of tangible personal property that has a useful life of more than two years and an acquisition cost of $500 or more. Any recipient may use its own definition of equipment, if its definition would at least include all items of equipment as defined here.

"*Public Assistance Programs*" means programs authorized by Titles I, IV-A, IV-B, IV-C, IV-D, IV-E, X, XIV, XVI (AABD) and XIX of the Social Security Act, and programs authorized by the Immigration and Nationality Act as amended by the Refugee Act of 1980 (Pub. L. 96-212).

"*State*" means the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Northern Mariana Islands and Guam.

"*State Agency*" means the State agency administering a public assistance program(s). This term includes local government public assistance agencies which administer public assistance programs under a State supervised system and the State agencies which supervise the local agencies.

§ 95.705 Equipment costs—Federal financial participation.

(a) *General rule.* In computing claims for Federal financial participation, equipment having a unit acquisition cost of $25,000 or less may be claimed in the period acquired or depreciated, at the option of the State agency. Equipment having a unit acquisition cost of more than $25,000 shall be depreciated. For purposes of this section, the term "depreciate" also includes use allowances computed in accordance with the cost principles precribed in Subpart Q of 45 CFR Part 74.

(b) *Exceptions.* (1) Equipment purchased under service agreements with other State agencies and under cost-type contracts shall be depreciated. However, equipment having a unit acquisition cost of $25,000 or less may be claimed in the period acquired if (a) the State agency approved the specific purchase and the claiming of the cost of the item, and (b) the contract or service agreement requires that the equipment or its residual value be transferred to the State agency when the equipment is no longer needed to carry out the work under the contract or service agreement.

(2) Reimbursement for ADP equipment having an acquisition cost in excess of $25,000 and subject to Subpart F of this part must be depreciated over its useful life unless otherwise specifically provided for by the Department. ADP equipment not subject to Subpart F is subject to the requirements of this subpart.

§ 95.707 Equipment management and disposition.

(a) An item of equipment is subject to the property rules in Subpart O of 45 CFR Part 74 if the total cost of the item was claimed in the period acquired and if the item was accepted for Federal financial participation as a direct cost under a single program or program activity. These rules also apply to ADP equipment where the State agency was permitted under Subpart F of this part to claim the total cost of the equipment in the period acquired.

(b) Other items of equipment whose costs are claimed for Federal financial participation (i.e., equipment that is capitalized and depreciated or is claimed in the period acquired and charged to more than one program) are not subject to the specific requirements in Subpart O of 45 CFR Part 74. However, the State agency is responsible for adequately managing the equipment, maintaining records on the equipment, and taking periodic physical inventories. Physical inventories may be made on the basis of statistical sampling. The following requirements apply to the disposition of this equipment:

(1) If the cost of the equipment was claimed in the period acquired and the equipment is later sold, the proceeds of the sale shall be credited to current expenditures in approximate proportion to the distribution of the equipment's cost.

(2) If the cost of the equipment was claimed in the period acquired and the equipment is later transferred to an activity which is not involved in the performance of programs currently or previously funded by the Federal Government, an amount equal to the fair market value of the Equipment on the date of the transfer shall be credited to current expenditures in approximate proportion to the distribution of the equipment's costs.

(3) If the cost of the equipment was claimed in the period acquired and the equipment is later traded in on other equipment claims for Federal financial participation in the costs of replacement equipment shall be limited to the additional outlay.

(4) If the equipment was depreciated, any gain or loss on the disposition of the equipment shall be treated as a decrease or an increase to the depreciation expense of the period in which the disposition takes place. This provision does not apply to equipment whose costs were claimed for Federal financial participation through use allowances.

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AUTHORITY: 42 U.S.C. 300w *et seq.*; 42 U.S.C. 300x *et seq.*; 42 U.S.C. 300y *et seq.*; 42 U.S.C. 701 *et seq.*; 42 U.S.C. 8621 *et seq.*; 42 U.S.C. 9901 *et seq.*; 42 U.S.C. 1397 *et seq.*; 31 U.S.C. 1243 *note*.

SOURCE: 47 FR 29486, July 6, 1982, unless otherwise noted.

Subpart A—Introduction

§ 96.1 Scope.

This part applies to the following block grant programs:

(a) Community services (Pub. L. 97-35, sections 671-682) (42 U.S.C. 9901-9912).

(b) Preventive health and health services (Pub. L. 97-35, section 901) (42 U.S.C. 300w-300w-8).

(c) Alcohol and drug abuse and mental health services (Pub. L. 97-35, section 901) (42 U.S.C. 300x-300x-9).

(d) Primary care (Pub. L. 97-35, section 901)(42 U.S.C. 300y-300y-10).

(e) Maternal and child health services (Pub. L. 97-35, sections 2191-94) (42 U.S.C. 1305).

(f) Social services (Pub. L. 97-35, sections 2351-55) (42 U.S.C. 1397-1397e).

(g) Low-income home energy assistance (Pub. L. 97-35, sections 2601-11) (42 U.S.C. 8621-8629).

§ 96.2 Definitions.

(a) "*Secretary*" means the Secretary of Health and Human Services or his designee.

(b) "*Department*" means the Department of Health and Human Services.

(c) "*Reconciliation Act*" means the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97-35).

(d) "*State*" includes the fifty states, the District of Columbia, and, as appropriate with respect to each block grant, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

[47 FR 29486, July 6, 1982, as amended at 52 FR 37965, Oct. 13, 1987]

§ 96.3 Information collection approval numbers.

Information collection requirements pertaining to the block grant programs have been approved by the

Office of Management and Budget under the provisions of the Paperwork Reduction Act, Pub. L. 96-511 (44 U.S.C. Chapter 35) and have been assigned OMB numbers:

0930-0080 Alcohol and Drug Abuse and Mental Health Services Block Grant Reporting Requirements
0920-0106 Preventive Health and Health Services Block Grant Reporting Requirements
0915-0023 Primary Care Block Grant Reporting Requirements
0915-0024 Maternal and Child Health Services Block Grant Reporting Requirements
0980-0125 Social Services Block Grant Reporting Requirements
0980-0126 Community Services Block Grant Reporting Requirements
0960-0261 Low-Income Home Energy Assistance Block Grant Reporting Requirements.

[47 FR 29486, July 6, 1982; 47 FR 43062, Sept. 30, 1982]

Subpart B—General Procedures

§ 96.10 Prerequisites to obtain block grant funds.

(a) No particular form is required for a State's application or the related submission required by statute. The provisions in section 1742(a) of the Reconciliation Act (31 U.S.C. 1243 note) relating to the contents of a report on proposed uses of funds must be satisfied; the specified information should be included in the plan required for the community services block grant (section 675(d) of the Reconciliation Act) (42 U.S.C. 9904(d)) and in the description of intended uses of funds required for the preventive health and health services, and alcohol and drug abuse and mental health services block grants (sections 1905(d) and 1915(d) of the Public Health Service Act (as amended by the Reconciliation Act) respectively (42 U.S.C. 300w-4(d) and 42 U.S.C. 300x-4(d)).

(b) The certifications required by the community services, primary care, preventive health and health services, alcohol and drug abuse and mental health services, and low-income home energy assistance block grant statutes to be made by the State's chief executive officer must be made by that individual personally, or by an individual authorized to make such certifications on behalf of the chief executive officer.

§ 96.11 Basis of award to the States.

The Secretary will award the block grant funds allotted to the State in accordance with the apportionment of funds from the Office of Management and Budget. Such awards will reflect amounts reserved for Indian Tribes and Tribal Organizations and, in FY 1982, any amounts awarded by the Department under transition authorities. The grant award constitutes the authority to carry out the program and to draw and expend funds.

[47 FR 29486, July 6, 1982; 47 FR 43062, Sept. 30, 1982]

§ 96.12 Grant payment.

The Secretary will make payments at such times and in such amounts to each State from its awards in advance or by way of reimbursement in accordance with section 203 of the Intergovernmental Cooperation Act (42 U.S.C. 4213) and Treasury Circular No. 1075 (31 CFR Part 205). When matching funds are involved, the Secretary shall take into account the ratio that such payment bears to such State's total expenditures under its awards.

§ 96.13 Reallotments.

The Secretary will re-allot to eligible States those funds available as of September 1 of each fiscal year under the reallotment provisions pertaining to the alcohol and drug abuse and mental health services, maternal and child health services, and preventive health and health services block grants. The reallotment procedure for the low-income home energy assistance block grant is specified in section 2607 of the Reconciliation Act (42 U.S.C. 8626) and § 96.81 of this part.

§ 96.14 Time period for obligation and expenditure of grant funds.

(a) *Obligations.* Amounts unobligated by the State at the end of the fiscal year in which they were first allotted shall remain available for obligation during the succeeding fiscal year for all block grants except:

(1) *Primary care.* Amounts are available only if the Secretary determines that the State acted in accordance with section 1926(a)(1) of the Public Health Service Act (42 U.S.C. 300y-5(a)(1)) and there is good cause for funds remaining unobligated.

(2) *Low-income home energy assistance.* Amounts are available only in accordance with 42 U.S.C. 8626(b)(2)(B). From allotments for fiscal year 1982 through fiscal year 1984, a maximum of 25 percent may be held available for the following fiscal year. Beginning with fiscal year 1985, a maximum of 15 percent of the amount payable to a State and not transferred to another block grant according to 42 U.S.C. 8623(f) may be held available for the next fiscal year. No funds may be obligated after the end of the fiscal year following the year for which they were allotted.

(b) *Expenditure.* No limitations exist on the time for expenditure of block grant funds, except those imposed by statute with respect to the community services, maternal and child health services, and social services block grants.

[47 FR 29486, July 6, 1982; 47 FR 43062, Sept. 30, 1982, as amended at 52 FR 37965, Oct. 13, 1987]

§ 96.15 Waivers.

Applications for waivers that are permitted by statute for the block grants should be submitted to the Assistant Secretary of Health in the case of the preventive health and health services, alcohol and drug abuse and mental health services, and maternal and child health services block grants; to the Director, Office of Community Services in the case of the community services block grant; and to the Assistant Secretary for Human Development Services in the case of the social services block grant. Beginning with fiscal year 1986, the Secretary's authority to waive the provisions of 42 U.S.C. 8624(b) under the low-income home energy assistance program is repealed.

[52 FR 37965, Oct. 13, 1987]

§ 96.16 Applicability of Title XVII of the Reconciliation Act (31 U.S.C. 7301-7305).

This section interprets the applicability of the general provisions governing block grants set forth in Title XVII of the Reconciliation Act (31 U.S.C. 7301-7305):

(a) Except as otherwise provided in this section or unless inconsistent with provisions in the individual block grant statutes, 31 U.S.C. 7301-7305 apply to the community services, preventive health and health services, and alcohol and drug abuse and mental health services block grants.

(b) The requirement in 31 U.S.C. 7303(b) relating to public hearings does not apply to any of the block grants governed by this part. Instead, the provisions in the individual block grant statutes apply.

(c) The maternal and child health services block grant is not subject to any requirements of 31 U.S.C. 7301-7305.

(d) The social services and low-income home energy assistance programs are subject only to 31 U.S.C. 7304.

(e) The audit provisions of 31 U.S.C. 7305 have, in most cases, been overridden by the Single Audit Act. Pub. L. 98-502, 31 U.S.C. 75, et seq., and do not apply to the block grants. Pursuant to § 96.31(b)(2), certain entities may, however, elect to conduct audits under the block grant audit provisions. For entities making this election, the provisions of 31 U.S.C. 7305 apply to the community services block grant.

(f) The applicability of 31 U.S.C. 7303(a) relating to the contents of a report on proposed uses of funds is specified in § 96.10.

[52 FR 37966, Oct. 13, 1987]

§ 96.17 Annual and biennial reporting deadlines.

Except for the low-income home energy assistance program activity reports, a State must make public and submit to the Department, each annual and biennial report required by statute:

(a) Within six months of the end of the period covered by the report; or

(b) At the time the State submits its application for funding for the Federal fiscal year which begins subsequent to the expiration of that six-month period.

These reports are required annually for preventive health and health services (42 U.S.C. 300w-5(a)(1)), alcohol and drug abuse and mental health services (42 U.S.C. 300x-5(a)(1)), and maternal and child health services (42 U.S.C. 706(a)(1)), and biennially for the social services block grant (42 U.S.C. 1397e(a)). See § 96.82 for requirements governing the submission of activity reports for the low-income home energy assistance program.

[52 FR 37966, Oct. 13, 1987]

Subpart C—Financial Management

§ 96.30 Fiscal and administrative requirements.

Except where otherwise required by Federal law or regulation, a State shall obligate and expend block grant funds in accordance with the laws and procedures applicable to the obligation and expenditure of its own funds. Fiscal control and accounting procedures must be sufficient to (a) permit preparation of reports required by the statute authorizing the block grant and (b) permit the tracing of funds to a level of expenditure adequate to establish that such funds have not been used in violation of the restrictions and prohibitions of the statute authorizing the block grant.

[47 FR 29486, July 6, 1982, as amended at 52 FR 37966, Oct. 13, 1987; 53 FR 11656, Apr. 8, 1988]

§ 96.31 Audits.

(a) *Fiscal periods beginning before January 1, 1985.* All block grant funds received in any grantee fiscal year beginning before January 1, 1985, are subject to the audit requirements set forth in each of the respective block grant statutes. Reports on the audit results for all fiscal years subject to this paragraph must be submitted to the Department within one year of the date of publication of this rule.

(b) *Fiscal periods beginning on or after January 1, 1985.* (1) Each State, local government, and Indian tribe or tribal organization that receives $100,000 or more (during the grantee's fiscal year) in all types of Federal financial assistance provided through the block grants and all other Federal programs must conduct an audit in accordance with the Single Audit Act, Pub. L. 98-502, 31 U.S.C. 75 *et seq.* The Office of Management and Budget has implemented the Single Audit Act through publication of OMB Circular A-128, which is set out in full at 45 CFR Part 74, Appendix J of the Department's Grant Administration Regulations. Grantees must comply with the requirements of 45 CFR Part 74, Appendix J.

(2) Each State, local government or Indian tribe or tribal organization that receives at least $25,000 and less than $100,000 in total Federal financial assistance from all sources must, at its option, audit block grant funds under either the Single Audit Act or the separate audit requirements set out in each respective block grant statute (or, in the case of the community services block grant, the requirements in 31 U.S.C. 7305). Any audit that is conducted under the block grant audit requirements must be conducted in accordance with standards that are consistent with the Comptroller General's standards for the audit of governmental organizations, programs, activities, and functions. Reports on the results of any such audit must be submitted to the Department by January 1, 1989, if the report is for an audit period that ended prior to January 1, 1988. Reports on the results of any such audit for an audit period that ends on January 1, 1988 or later must be submitted to the Department within one year of the end of the audit period.

(c) *Submission of audit reports.* Reports of audits conducted under either the Single Audit Act or the block grant statutes shall, if required to be submitted to the Department, be submitted to the Regional Inspector General for Audit responsible for the Federal region in which the block grant recipient is located.

[52 FR 37966, Oct. 13, 1987, as amended at 53 FR 6828, Mar. 3, 1988]

§ 96.32 Financial settlement.

The State must repay to the Department amounts found after audit resolution to have been expended improperly. In the event that repayment is not made voluntarily, the Department will undertake recovery.

[52 FR 37966, Oct. 13, 1987]

§ 96.33 Referral of cases to the Inspector General.

State or tribal officials who have information indicating the commission or potential commission of fraud or other offenses against the United States involving block grant funds should promptly provide the information to the appropriate Regional Office of Investigations of the Department's Office of the Inspector General.

[52 FR 37966, Oct. 13, 1987]

Subpart D—Direct Funding of Indian Tribes and Tribal Organizations

§ 96.40 Scope.

This subpart applies to the community services, alcohol and drug abuse and mental health services, preventive health and health services, primary care, and low-income home energy assistance block grants.

§ 96.41 General determination.

(a) The Secretary has determined that Indian tribes and tribal organizations would be better served by means of grants provided directly by the Secretary to such tribes and organizations out of the State's allotment of block grant funds than if the State were awarded its entire allotment. Accordingly, where provided for by statute, the Secretary will, upon request of an eligible Indian tribe or tribal organization, reserve a portion of a State's allotment and, upon receipt of the complete application and related submission that meets statutory requirements, grant it directly to the tribe or organization.

(b) An Indian tribe or tribal organization may request direct funding under a block grant program included in this subpart regardless of whether the State in which it is located is receiving funds under the block grant program.

§ 96.42 General procedures and requirements.

(a) An Indian tribe or tribal organization applying for or receiving direct funding from the Secretary under a block grant program shall be subject to all statutory and regulatory requirements applicable to a State applying for or receiving block grant funds to the extent that such requirements are relevant to an Indian tribe or tribal organization except where otherwise provided by statute or in this part.

(b) A tribal organization representing more than one Indian tribe will be eligible to receive block grant funds on behalf of a particular tribe only if the tribe has by resolution authorized the organization's action.

(c) If an Indian tribe or tribal organization whose service population resides in more than one State applies for block grant funds that, by statute, are apportioned on the basis of population, the allotment awarded to the tribe or organization shall be taken from the allotments of the various States in which the service population resides in proportion to the number of eligible members or households to be served in each State. If block grant funds are required to be apportioned on the basis of grants during a base year, the allotment to the Indian tribe or tribal organization shall be taken from the allotment of the State whose base year grants included the relevant grants to the tribe or organization.

(d) The audit required under the block grant programs shall be conducted by an entity that is independent of the Indian tribe or tribal organization receiving grant funds from the Secretary.

(e) Beginning with fiscal year 1983, any request by an Indian tribe or tribal organization for direct funding by the Secretary must be submitted to the Secretary, together with the required application and related materials, by September 1 preceding the Federal fiscal year for which funds are sought. A separate application is required for each block grant. After the

September 1 deadline, tribal applications will be accepted only with the concurrence of the State (or States) in which the tribe or tribal organization is located.

(f) A State receiving block grant funds is not required to use those funds to provide tangible benefits (e.g., cash or goods) to Indians who are within the service population of an Indian tribe or tribal organization that received direct funding from the Department under the same block grant program for the same fiscal year. A State, however, may not deny Indians access to intangible services funded by block grant programs (e.g., treatment at a community health center) even if the Indians are members of a tribe receiving direct funding for a similar service.

[47 FR 29486, July 6, 1982, as amended at 52 FR 37966, Oct. 13, 1987]

§ 96.43 Procedures during FY 1982.

(a) This section applies to the fiscal year beginning October, 1, 1981.

(b) A request for direct funding must be received by the Secretary before the Secretary has awarded all of the allotment to the State involved. The application and related submission may be submitted later but must be submitted within 75 days after the beginning of the quarter in which the State qualified for block grant funds, (or by August 20, 1982 in the case of an Indian tribe located in a State that has not qualified for block grant funds in FY 1982) except that the application and related submission for the low-income home energy assistance program must be submitted by December 15, 1981. A separate request and application are required for each block grant.

[47 FR 29486, July 6, 1982; 47 FR 43062, Sept. 30, 1982]

§ 96.44 Community services.

(a) This section applies to direct funding of Indian tribes and tribal organizations under the community services block grant.

(b) The terms "Indian tribe" and "tribal organization" as used in the Reconciliation Act have the same meaning given such terms in section 4(b) and 4(c) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b). The terms also include organized groups of Indians that the State in which they reside has determined are Indian tribes. An organized group of Indians is eligible for direct funding based on State recognition if the State has expressly determined that the group is an Indian tribe. In addition, the statement of the State's chief executive officer verifying that a tribe is recognized by that State will also be sufficient to verify State recognition for the purpose of direct funding.

(c) For purposes of section 674(c)(2) of the Act (42 U.S.C. 9903(c)(2)) an "eligible Indian" means a member of an Indian tribe whose income is at or below the poverty line defined in section 673(2) of the Act (42 U.S.C. 9902(2)). An "eligible individual" under section 674(c)(2) of the Reconciliation Act (42 U.S.C. 9903(c)(2)) means a resident of the State whose income is at or below the poverty line.

(d) An Indian tribe or tribal organization will meet the requirements of section 675(c)(1) (42 U.S.C. 9904(c)(1)) if it certifies that it agrees to use the funds to provide at least one of the services or activities listed in that section.

(e) An Indian tribe or tribal organization is not required to comply with section 675(b) (42 U.S.C. 9904(b)) or to provide the certifications required by the following other provisions of the Reconciliation Act.

(1) Section 675(c)(2)(A) (42 U.S.C. 9904(c)(2)(A));

(2) Section 675(c)(3) (42 U.S.C. 9904(c)(3)); and

(3) Section 675(c)(4) (42 U.S.C. 9904(c)(4)).

(4) Section 675(c)(11) (42 U.S.C. 9904(c)(11)).

(f) In each fiscal year, Indian tribes and tribal organizations may expend for administrative expenses—comparable to the administrative expenses incurred by State at the State level—an amount not to exceed the greater of the amounts determined by:

(1) Multiplying their allotment under section 674 of the Reconcilia-

tion Act (42 U.S.C. 9903) by five percent; or

(2) Multiplying the allotment by the percentage represented by the ratio of $55,000 to the smallest State allotment (excluding territorial allotments) for that fiscal year.

[47 FR 29486, July 6, 1982, as amended at 52 FR 37967, Oct. 13, 1987]

§ 96.45 Preventive health and health services.

(a) This section applies to direct funding of Indian tribes and tribal organizations under the preventive health and health services block grant.

(b) For the purposes of determining eligible applicants under section 1902(d) of the Public Health Service Act, a grantee that received a grant directly from the Secretary in FY 1981 under any of the programs replaced by the preventive health and health services block grant that was specifically targeted toward serving a particular Indian tribe or tribal organization will be considered eligible if the grantee is an Indian tribe or tribal organization at the time it requests funds under this part. Grantees that received funds under formula or Statewide grants, and subgrantees that received funds from any program replaced by the preventive health and health services block grant, are not eligible.

§ 96.46 Alcohol and drug abuse and mental health services.

(a) This section applies to direct funding of Indian tribes and tribal organizations under the alcohol and drug abuse and mental health services block grant.

(b) For the purpose of determining eligible applicants under section 1912(c) of the Public Health Service Act (42 U.S.C. 300x-1(c)) an entity that received a treatment grant or contract directly from the Secretary in FY 1980 specifically targeted toward serving a particular Indian tribe or tribal organization will be considered eligible if the entity is an Indian tribe or tribal organization at the time it requests funds under this part. Entities that received funds under formula or statewide grants, and those grantees who had the responsibility for their treatment grant support transferred to the Indian Health Service, are not eligible.

(c) An Indian tribe or tribal organization is not required to comply with section 1916(b) (42 U.S.C. 300x-5(b) or to provide the certifications required by section 1916(c)(2) through (8) and (13) through (15) of the Public Health Service Act (42 U.S.C. 300x-4 (c)(2) through (c)(8) and (c)(13) through (c)(15)). Also, the service identified in section 1915(a)(1) (42 U.S.C. 300x-3 (a)(1)) need not be provided by means of grants to community mental health centers.

[47 FR 29486, July 6, 1982, as amended at 52 FR 37967, Oct. 13, 1987]

§ 96.47 Primary care.

Applications for direct funding of Indian tribes and tribal organizations under the primary care block grant must comply with 42 CFR Part 51c (Grants for Community Health Services).

§ 96.48 Low-income home energy assistance.

(a) This section applies to direct funding of Indian tribes under the low-income home energy assistance program.

(b) The terms "Indian tribe" and "tribal organization" as used in the Reconciliation Act have the same meaning given such terms in section 4(b) and 4(c) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b) except that the terms shall also include organized groups of Indians that the State in which they reside has expressly determined are Indian tribes or tribal organizations in accordance with State procedures for making such determinations.

(c) For purposes of section 2604(d) of the Act (42 U.S.C. 8623(d)), an organized group of Indians is eligible for direct funding based on State recognition if the State has expressly determined that the group is an Indian tribe. A statement by the State's chief executive officer verifying that a tribe is recognized by that State will also be sufficient to verify State recognition for the purpose of direct funding.

(d) The plan required by section 2604(d)(4) of the Reconciliation Act (42 U.S.C. 8623(d)(4)) shall contain the certification and information required for States under section 2605 (b) and (c) of that Act (42 U.S.C. 8624 (b) and (c)). An Indian tribe or tribal organization is not required to comply with section 2605(a)(2) of the Act (42 U.S.C. 8624(a)(2)).

(e) Where a tribe requests that the Secretary fund another entity to provide energy assistance for tribal members, as provided by section 2604(d)(3) of the Act (42 U.S.C. 8623(d)(3)), the Secretary shall consider the following factors in selecting the grantee: the ability of the other entity to provide low-income home energy assistance, existing tribal-State agreements as to the size and location of the service population, and the history of State services to the Indian people to be served by the other entity.

Subpart E—Enforcement

§ 96.50 Complaints.

(a) This section applies to any complaint (other than a complaint alleging violation of the nondiscrimination provisions) that a State has failed to use its allotment under a block grant in accordance with the terms of the act establishing the block grant or the certifications and assurances made by the State pursuant to that act. The Secretary is not required to consider a complaint unless it is submitted as required by this section.

(b) Complaints with respect to the health block grants must be submitted in writing to either the Assistant Secretary for Health or: For the preventive health and health services block grant, the Director, Centers for Disease Control; for the alcohol and drug abuse and mental health services block grant, the Administrator, Alcohol, Drug Abuse, and Mental Health Administration; for the maternal and child health services block grant, the Administrator, Health Resources and Services Administration. Complaints with respect to the social services block grant must be submitted in writing to the Assistant Secretary for Human Development Services. Complaints with respect to the low-income home energy assistance program and the community services block grant must be submitted in writing to the Director, Office of Community Services. (The address for the Director, Center for Disease Control is 1600 Clifton Road, NE., Atlanta, Georgia 30333. For each of the other officials cited above the address is 200 Independence Avenue SW., Washington, DC 20201.) The complaint must identify the provision of the act, assurance, or certification that was allegedly violated; must specify the basis for the violations it charges; and must include all relevant information known to the person submitting it.

(c) The Department shall promptly furnish a copy of any complaint to the affected State. Any comments received from the State within 60 days (or such longer period as may be agreed upon between the State and the Department) shall be considered by the Department in responding to the complaint. The Department will conduct an investigation of complaints where appropriate.

(d) The Department will provide a written response to complaints within 180 days after receipt. If a final resolution cannot be provided at that time, the response will state the reasons why additional time is necessary.

(e) The Department recognizes that under the block grant programs the States are primarily responsible for interpreting the governing statutory provisions. As a result, various States may reach different interpretations of the same statutory provisions. This circumstance is consistent with the intent of and statutory authority for the block grant programs. In resolving any issue raised by a complaint or a Federal audit the Department will defer to a State's interpretation of its assurances and of the provisions of the block grant statutes unless the interpretation is clearly erroneous. In any event, the Department will provide copies of complaints to the independent entity responsible for auditing the State's activities under the block grant program involved. Any determination by the Department that a State's interpretation is not clearly erroneous shall not preclude or otherwise prejudice the State auditors' consideration of the question.

[47 FR 29486, July 6, 1982; 47 FR 43062, Sept. 30, 1982, as amended at 52 FR 37967, Oct. 13, 1987]

§ 96.51 Hearings.

(a) The Department will order a State to repay amounts found not to have been expended in accordance with law of the certifications provided by the State only after the Department has provided the State notice of the order and an opportunity for a hearing. Opportunity for a hearing will not be provided, however, when the State, in resolving audit findings or at another time, has agreed that the amounts were not expended in accordance with law or the certifications. The hearing will be governed by Subpart F of this part and will be held in the State if required by statute.

(b) If a State refuses to repay amounts after a final decision that is not subject to further review in the Department, the amounts may be offset against payments to the State. If a statute requires an opportunity for a hearing before such an offset may be made, the hearing will be governed by Subpart F of this part and will be held in the State if required by statute.

(c) The Department will withhold funds from a State only if the Department has provided the State an opportunity for a hearing. The hearing will be governed by Subpart F of this part and will be held in the State if required by statute.

[47 FR 29486, July 6, 1982, as amended at 52 FR 37967, Oct. 13, 1987]

§ 96.52 Appeals.

(a) Decisions resulting from repayment hearings held pursuant to § 96.51(a) of this part may be appealed by either the State or the Department to the Grant Appeals Board.

(b) Decisions resulting from offset hearings held pursuant to § 96.51(b) of this part may not be appealed.

(c) Decisions resulting from withholding hearings held pursuant to § 96.51(c) of this part may be appealed to the Secretary by the State or the Department as follows:

(1) An application for appeal must be received by the Secretary no later than 60 days after the appealing party receives a copy of the presiding officer's decision. The application shall clearly identify the questions for which review is sought and shall explain fully the party's position with respect to those questions. A copy shall be furnished to the other party.

(2) The Secretary may permit the filing of opposing briefs, hold informal conferences, or take whatever other steps the Secretary finds appropriate to decide the appeal.

(3) The Secretary may refer an application for appeal to the Grant Appeals Board. Notwithstanding Part 16 of this title, in the event of such a referral, the Board shall issue a recommended decision that will not become final until affirmed, reversed, or modified by the Secretary.

(d) Any appeal to the Grant Appeals Board under this section shall be governed by Part 16 of this title except that the Board shall not hold a hearing. The Board shall accept any findings with respect to credibility of witnesses made by the presiding officer. The Board may otherwise review and supplement the record as provided for in Part 16 of this title and decide the issues raised.

Subpart F—Hearing Procedure

§ 96.60 Scope.

The procedures in this subpart apply when opportunity for a hearing is provided for by § 96.51 of this part.

§ 96.61 Initiation of hearing.

(a) A hearing is initiated by a notice of opportunity for hearing from the Department. The notice will:

(1) Be sent by mail, telegram, telex, personal delivery, or any other mode of written communication;

(2) Specify the facts and the action that are the subject of the opportunity for a hearing;

(3) State that the notice of opportunity for hearing and the hearing are governed by these rules; and

(4) State the time within which a hearing may be requested, and state the name, address, and telephone

number of the Department employee to whom any request for hearing is to be addressed.

(b) A State offered an opportunity for a hearing has the amount of time specified in the notice, which may not be less than 10 days after receipt of the notice, within which to request a hearing. The request may be filed by mail, telegram, telex, personal delivery, or any other mode of written communication, addressed to the designated Department employee. If no response is filed within that time, the offer is deemed to have been refused and no hearing will be held.

(c) If a hearing is requested, the Department will designate a presiding officer, and (subject to § 96.51 of this part) the hearing will take place at a time and location agreed upon by the State requesting the hearing, the Department, and the presiding officer or, if agreement cannot be reached, at a reasonable time and location designated by the presiding officer.

§ 96.62 Presiding officer.

(a) A Department employee to whom the Secretary delegates such authority, or any other agency employee designated by an employee to whom such authority is delegated, may serve as the presiding officer and conduct a hearing under this subpart.

(b) The presiding officer is to be free from bias or prejudice and may not have participated in the investigation or action that is the subject of the hearing or be subordinate to a person, other than the Secretary, who has participated in such investigation or action.

(c) The Secretary is not precluded by this section from prior participation in the investigation or action that is the subject of the hearing.

(d) A different presiding officer may be substituted for the one originally designated under § 96.61 of this part without notice to the parties.

§ 96.63 Communications to presiding officer.

(a) Those persons who are directly involved in the investigation or presentation of the position of the Department or any party at a hearing that is subject to this subpart should avoid any off-the-record communication on the matter to the presiding officer or his advisers if the communication is inconsistent with the requirement of § 96.68 of this part that the administrative record be the exclusive record for decision. If any communication of this type occurs, it is to be reduced to writing and made part of the record, and the other party provided an opportunity to respond.

(b) A copy of any communications between a participant in the hearing and the presiding officer, e.g., a response by the presiding officer to a request for a change in the time of the hearing is to be sent to all parties by the person initiating the communication.

§ 96.64 Intervention.

Participation as parties in the hearing by persons other than the State and the Department is not permitted.

§ 96.65 Discovery.

The use of interrogatories, depositions, and other forms of discovery shall not be allowed.

§ 96.66 Hearing procedure.

(a) A hearing is public, except when the Secretary or the presiding officer determines that all or part of a hearing should be closed to prevent a clearly unwarranted invasion of personal privacy (such as disclosure of information in medical records that would identify patients), to prevent the disclosure of a trade secret or confidential commercial or financial information, or to protect investigatory records compiled for law enforcement purposes that are not available for public disclosure.

(b) A hearing will be conducted by the presiding officer. Employees of the Department will first give a full and complete statement of the action which is the subject of the hearing, together with the information and reasons supporting it, and may present any oral or written information relevant to the hearing. The State may then present any oral or written information relevant to the hearing. Both parties may confront and conduct reasonable cross-examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing.

(c) The hearing is informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views will be made or considered, but either party may comment upon or rebut all such data, information, and views.

(d) The presiding officer may order the hearing to be transcribed. The State may have the hearing transcribed, at the State's expense, in which case a copy of the transcript is to be furnished to the Department at the Department's expense.

(e) The presiding officer may, if appropriate, allow for the submission of post-hearing briefs. The presiding officer shall prepare a written decision, which shall be based on a preponderance of the evidence, shall include a statement of reasons for the decision, and shall be final unless appealed pursuant to § 96.52 of this part. If post-hearing briefs were not permitted, the parties to the hearing will be given the opportunity to review and comment on the presiding officer's decision prior to its being issued.

(f) The presiding officer shall include as part of the decision a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue.

(g) The presiding officer shall furnish a copy of the decision to the parties.

(h) The presiding officer has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct a fair, expeditious, and impartial hearing, and to enforce the requirements of this subpart concerning the conduct of hearings. The presiding officer may direct that the hearing be conducted in any suitable manner permitted by law and these regulations.

(i) The Secretary or the presiding officer has the power to suspend, modify, or waive any provision of this subpart.

§ 96.67 Right to counsel.

Any party to a hearing under this part has the right at all times to be advised and accompanied by counsel.

§ 96.68 Administrative record of a hearing.

(a) The exclusive administrative record of the hearing consists of the following:

(1) The notice of opportunity for hearing and the response.

(2) All written information and views submitted to the presiding officer at the hearing or after if specifically permitted by the presiding officer.

(3) Any transcript of the hearing.

(4) The presiding officer's decision and any briefs or comments on the decision under § 96.66(e) of this part.

(5) All letters or communications between participants and the presiding officer or the Secretary referred to in § 96.63 of this part.

(b) The record of the hearing is closed to the submission of information and views at the close of the hearing, unless the presiding officer specifically permits additional time for a further submission.

Subpart G—Social Services Block Grants

§ 96.70 Scope.

This subpart applies to the social services block grant.

§ 96.71 Definitions.

(a) Section 2005 (a)(2) and (a)(5) (42 U.S.C. 1397d (a)(2) and (a)(5)) of the Social Security Act establishes prohibitions against the provision of room and board and medical care unless, among other reasons, they are an "integral but subordinate" part of a State-authorized social service. "Integral but subordinate" means that the room and board provided for a short term or medical care is a minor but essential adjunct to the service of which it is a part and is necessary to achieve the objective of that service. Room and board provided for a short term shall not be considered an integral but subordinate part of a social service when it is provided to an individual in a foster family home or other facility the primary purpose of which is to provide food, shelter, and care or supervision, except for temporary emergency shelter provided as a protective service.

(b) As used in section 2005(a)(5) of the Social Security Act (42 U.S.C. 1397d (a)(5)) with respect to the limitations governing the provision of services by employees of certain institutions, "employees" includes staff, contractors, or other individuals whose activities are under the professional direction or direct supervision of the institution.

[47 FR 29486, July 6, 1982; 47 FR 43062, Sept. 30, 1982]

§ 96.72 Transferability of funds.

Under section 2002(d) of the Social Security Act (42 U.S.C. 1397a(d)), funds may be transferred in accordance with the provisions of that section to the preventive health and health services, alcohol and drug abuse and mental health services, primary care, maternal and child health services, and low-income home energy assistance block grants. In addition, funds may be transferred to other Federal block grants for support of health services, health promotion and disease prevention activities, or low-income home energy assistance (or any combination of those activities).

§ 96.73 Sterilization.

If a State authorizes sterilization as a family planning service, it must comply with the provisions of 42 CFR Part 441, Subpart F, except that the State plan requirement under 42 CFR 441.252 does not apply.

[47 FR 33702, Aug. 4, 1982]

Subpart H—Low-income Home Energy Assistance Program

§ 96.80 Scope.

This subpart applies to the low-income home energy assistance program.

§ 96.81 Reallotment report.

As a part of the reallotment procedure established by 42 U.S.C. 8626, beginning with funds to be held available for fiscal year 1986, each recipient of funds must submit a report to the Secretary by August 1 of each year containing the following information:

(a) The amount of funds that the State desires remain available for obligation in the succeeding fiscal year, not to exceed 15 percent of the funds payable to the State and not transferred pursuant to 42 U.S.C. 8623(f);

(b) A statement of the reasons that this amount to remain available will not be used in the fiscal year for which it was allotted;

(c) A description of the types of assistance to be provided with the amount held available; and

(d) The amounts of funds, if any, to be subject to reallotment.

(Approved by the Office of Management and Budget under control number 0960-0446)

[52 FR 37967, Oct. 13, 1987]

§ 96.82 Required report.

In accordance with 42 U.S.C. 8629(a), each State receiving funds shall submit to the Department by October 31 of each year a report of:

(a) The number and income levels of the households assisted by LIHEAP funds during the preceding fiscal year; and

(b) The number of households assisted by LIHEAP funds during the preceding fiscal year that contain one or more individuals who are 60 years or older and the number which contain one or more individuals who are handicapped.

(Approved by the Office of Management and Budget under control number 0960-0446)

[52 FR 37967, Oct. 13, 1987]

§ 96.83 [Reserved]

§ 96.84 Territories.

Except as otherwise provided, a territory eligible for funds shall have the same rights and responsibilities as a State.

§ 96.85 Income eligibility.

(a) *Application of poverty income guidelines.* In implementing the income eligibility standards in section 2605(b)(2) of Pub. L. 97-35 (42 U.S.C.

8624), grantees using the Federal Government's official poverty income guidelines as a basis for determining eligibility for assistance shall, by October 1 each year, adjust their income eligibility criteria so that they are in accord with the most recently published update of the guidelines. Grantees may adjust their income eligibility criteria to accord with the most recently published revision to the poverty income guidelines at any time between publication of the revision and the following October 1.

(b) *Adjustment of annual median income for household size.* In order to determine the State median income for households that have other than four individuals, grantees shall adjust the State median income figures (published annually by the Secretary), by the following percentages:

(1) One-person household, 52 percent;

(2) Two-person household, 68 percent;

(3) Three-person household, 84 percent;

(4) Four-person household, 100 percent;

(5) Five-person household, 116 percent;

(6) Six-person household, 132 percent; and

(7) For each additional household member above six persons, add three percentage points to the percentage adjustment for a six-person household.

[53 FR 6827, Mar. 3, 1988]

§ 96.86 State plans.

The assurances in section 2605(b) of Pub. L. 97-35, as amended, pertain to all forms of assistance provided by the State.

[52 FR 37967, Oct. 13, 1987]

§ 96.87 Prevention of waste, fraud and abuse.

States and Indian tribes must establish appropriate systems and procedures to prevent, detect and correct waste, fraud and abuse in activities funded under the low-income home energy assistance program. The systems and procedures are to address possible waste, fraud and abuse by clients, vendors and administering agencies.

[52 FR 37967, Oct. 13, 1987]

§ 96.88 Administrative costs.

(a) *Costs of planning and administration.* Any expenditure for governmental functions normally associated with administration of a public assistance program must be included in determining administrative costs subject to the statutory limitation on administrative costs, regardless of whether the expenditure is incurred by the State, a subrecipient, a grantee, or a contractor of the State.

(b) *Administrative costs for territories and Indian tribes.* For Indian tribes, tribal organizations and territories with allotments of $20,000 or less, the limitation on the cost of planning and administering the low-income home energy assistance program shall be 20 percent of funds payable and not transferred for use under another block grant. For tribes, tribal organizations and territories with allotments over $20,000, the limitation on the cost of planning and administration shall be $4,000 plus 10% of the amount of funds payable (and not transferred for use under another block grant) that exceeds $20,000.

[52 FR 37967, Oct. 13, 1987]

§ 96.89 Exemption from standards for providing energy crisis intervention assistance.

The performance standards in section 2604(c) of Pub. L. 97-35 (42 U.S.C. 8623), as amended by section 502(a) of the Human Services Reauthorization Act of 1986 (Pub. L. 99-425)—concerning provision of energy crisis assistance within specified time limits, acceptance of applications for energy crisis benefits at geographically accessible sites, and provision to physically infirm low-income persons of the means to apply for energy crisis benefits at their residences or to travel to application sites—shall not apply under the conditions described in this section.

(a) These standards shall not apply to a program in a geographical area affected by (1) a major disaster or emergency designated by the President under the Disaster Relief Act of 1974, or (2) a natural disaster identified by the chief executive officer of a State, territory, or direct-grant Indian tribe or tribal organization, if the Secretary (or his or her designee) determines that the disaster or emergency makes compliance with the standards impracticable.

(b) The Secretary's determination will be made after communication by the chief executive officer (or his or her designee) to the Secretary (or his or her designee) of the following:

(1) Information substantiating the existence of a disaster or emergency;

(2) Information substantiating the impracticability of compliance with the standards, including a description of the specific conditions caused by the disaster or emergency which make compliance impracticable; and

(3) Information on the expected duration of the conditions that make compliance impracticable.

If the communication is made by the chief executive officer's designee and the Department does not have on file written evidence of the designation, the communication must also include:

(4) Evidence of the appropriate delegation of authority.

(c) The initial communication by the chief executive officer may be oral or written. If oral, it must be followed as soon as possible by written communication confirming the information provided orally. The Secretary's exemption initially may be oral. If so, the Secretary will provide written confirmation of the exemption as soon as possible after receipt of appropriate written communication from the chief executive officer.

(d) Exemption from the standards shall apply from the moment of the Secretary's determination, only in the geographical area affected by the disaster or emergency, and only for so long as the Secretary determines that the disaster or emergency makes compliance with the standards impracticable.

[53 FR 6827, Mar. 3, 1988]

Subpart I—Community Services Block Grants

§ 96.90 Scope.

This subpart applies to the community services block grant.

§ 96.91 Audit requirement.

Pursuant to section 1745(b) of the Reconciliation Act (31 U.S.C. 1243 note) an audit is required with respect to the 2-year period beginning on October 1, 1981, and with respect to each 2-year period thereafter. In its application for funds, a State may modify the assurance required by section 675(c)(9) of the Reconciliation Act (42 U.S.C. 9904(c)(9)) to conform to the requirements of section 1745(b).

§ 96.92 Termination of funding.

Where a State determines pursuant to section 675(c)(11) of the Community Services Block Grant Act that it will terminate present or future funding of any community action agency or migrant and seasonal farmworker organization which received funding in the previous fiscal year, the State must provide the organization with notice and an opportunity for hearing on the record prior to terminating funding. If a review by the Secretary of the State's final decision to terminate funding is requested pursuant to section 676A, the request must be made in writing, within 30 days of notification by the State of its final decision to terminate funding. The Department will confirm or reject the State's finding of cause, normally within 90 days. If a request for a review has been made, the State may not discontinue present or future funding until the Department confirms the State's finding of cause. If no request for a review is made within the 30-day limit, the State's decision will be effective at the expiration of that time.

[52 FR 37968, Oct. 13, 1987]

Subpart J—Primary Care Block Grants

§ 96.100 Scope.

This subpart applies to the primary care block grant.

§ 96.101 Review of a State decision to discontinue funding a community health center.

Where a State determines for FY 1983, pursuant to section 1926(a)(2) of the Public Health Service Act (42 U.S.C. 300y-5(a)(2)), that a community health center does not meet the criteria for continued funding set forth in section 330 of the Public Health Service Act (42 U.S.C. 254c), the State must advise the Department of the decision and the basis upon which it was made. The Department will permit the center 30 days to respond to the State's determination. After evaluating the reasons advanced by the State and the center, the Department will determine within 30 days after the center's response is due whether the center meets the requirements for receiving a grant under the Public Health Service Act. The State may not discontinue funding the center until the Department has completed its review.

[47 FR 29486, July 6, 1982; 47 FR 43062, Sept. 30, 1982]

§ 96.102 Carryover of unobligated funds.

In implementing section 1925(a)(2) of the Public Health Service Act (42 U.S.C. 300y-4(a)(2)), the Secretary will determine that there is good cause for funds remaining unobligated if planned obligations could not be carried out because of a bona fide reason or if the State has determined that program objectives would be better served by deferring obligation of the funds to the following year.

Subpart K—Transition Provisions

§ 96.110 Scope.

Except as otherwise stated, this subpart applies to the community services, preventive health and health services, alcohol and drug abuse and mental health services, and maternal and child health services block grants for the fiscal year beginning October 1, 1981. The social services block grant and the low-income home energy assistance program are not subject to the provisions of this subpart.

§ 96.111 Continuation of pre-existing regulations.

The regulations previously issued by the Department and the Community Services Administration to govern administration of the programs replaced by the block grants specified in § 96.1 of this part shall continue in effect until revised to govern administration of those programs by the Department in those circumstances in which States have not qualified for block grants.

§ 96.112 Community services block grant.

(a) For the fiscal year beginning October 1, 1981, only, a State may choose to operate programs under the community services block grant or, instead, have the Secretary operate the programs replaced by the block grant. If a State does not notify the Secretary in accordance with the statutory deadlines each quarter, it will be deemed to have requested the Secretary to operate the programs for the following quarter.

(b) A State or territory that does not have any eligible entity" as that term is defined in section 673(1) of the Reconciliation Act (42 U.S.C. 9902), as amended by section 17 of Pub. L. 97-115 (December 19, 1981), or any other entity for which funding is allowed under section 138 of Pub. L. 97-276, may distribute its allotment for the Fiscal Year beginning October 1, 1982 according to section 675(c)(2)(A)(ii) of the Reconciliation Act.

(c) For any quarter in which the Secretary administers the programs, the Department's administration costs will be deducted from the State's allotment. The Department's total administration costs for making grants during fiscal year 1982 and for any monitoring of these grants in fiscal year 1983 will be deducted from each State's allotment in proportion to the total amount of grants awarded from the allotment during the period of administration by the Department (but not to exceed 5 percent of the State's fiscal year 1982 allotment).

[47 FR 29486, July 6, 1982, as amended at 48 FR 9271, Mar. 4, 1983]

Subpart L—Alcohol and Drug Abuse and Mental Health Services Block Grant

§ 96.120 Scope.

This subpart applies to the alcohol and drug abuse and mental health services block grant.

[52 FR 37968, Oct. 13, 1987. Redesignated at 53 FR 11656, Apr. 8, 1988]

§ 96.121 Earmarks.

For the purposes of determining whether a State has initiated a new or expanded service within the meaning of the earmarks set out in sections 1916(c)(14) and 1916(c)(15) of the Public Health Service Act, a service will be considered "new" or "expanded" to the extent that it exceeds funds expended by the State in fiscal year 1984.

[52 FR 37968, Oct. 13, 1987. Redesignated at 53 FR 11656, Apr. 8, 1988]

PART 97—CONSOLIDATION OF GRANTS TO THE INSULAR AREAS

Sec.
97.10 What is a consolidated grant?
97.11 Which jurisdictions may apply for a consolidated grant?
97.12 Which grants may be consolidated?
97.13 How does an insular area apply for a consolidated grant?
97.14 How will grant awards be made?
97.15 For what purposes can grant funds be used?
97.16 What fiscal, matching and administrative requirements apply to grantees?

AUTHORITY: Sec. 501, Pub. L. 95-134, 91 Stat. 1164, amended, sec. 9, Pub. L. 95-348, 92 Stat. 495, sec. 601, Pub. L. 96-205, 94 Stat. 90 (48 U.S.C. 1469a).

SOURCE: 47 FR 56468, Dec. 16, 1982, unless otherwise noted.

§ 97.10 What is a consolidated grant?

As used in this part, a "consolidated grant" means a grant award to an insular area, the funds of which are derived from the allocations under two or more of the programs specified in § 97.12.

§ 97.11 Which jurisdictions may apply for a consolidated grant?

The following jurisdictions ("insular areas"), as appropriate with respect to each block and formula grant program, may apply for a consolidated grant under this Part: The Virgin Islands, Guam, American Samoa, the Comonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands which consists of the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.

[52 FR 9495, Mar. 25, 1987]

§ 97.12 Which grants may be consolidated?

These regulations apply to the consolidation of grants under the following programs:

TITLE AND STATUTORY CITATION

Block Grants

(a) Preventive Health and Health Services, 42 U.S.C. 300w–300w-8.

(b) Alcohol and Drug Abuse and Mental Health Services, 42 U.S.C. 300x–300x-9.

(c) Maternal and Child Health Services, 42 U.S.C. 701–709.

(d) Social Services, 42 U.S.C. 1397–1397f.

(e) Community Services, 42 U.S.C. 9901–9912.

(f) Low-Income Home Energy Assistance, 42 U.S.C. 8621–8629.

Other Grants

(g) Child Welfare Services, 42 U.S.C. 620, et seq.

(h) Developmental Disabilities, 42 U.S.C. 6061–6068.

(i) Aging Supportive Services and Senior Centers, 42 U.S.C. 3030d.

(j) Congregate Meals for the Elderly, 42 U.S.C. 3030e.

(k) Home Delivered Meals for the Elderly, 42 U.S.C. 3030f.

(l) Child Abuse and Neglect State Grants, 42 U.S.C. 5103(b).

(m) Dependent Care Planning and Development State Grants, 42 U.S.C. 9871, et. seq.

(n) Family Violence Prevention and Services, 42 U.S.C. 10401, et seq.

(o) Children's Justice Act, 42 U.S.C. 5101, et seq.

(p) Child Development Associate Scholarship Assistance Act, 42 U.S.C. 10901, et seq.

[52 FR 9495, Mar. 25, 1987]

§ 97.13 How does an insular area apply for a consolidated grant?

(a) An insular area may apply for a consolidated grant in lieu of filing an individual application for any of the programs listed in § 97.12 for which the insular area is eligible.

(b) The chief executive officer or his designee may submit a consolidated grant application at any time prior to expenditure of the funds proposed for consolidation. The application must specify the amount of funds proposed for consolidation, the titles of the programs that are the sources of funds that are to be consolidated and the titles of the programs under whose statutory authority the funds are to be expended.

(c) The application must contain the assurances, certifications, and other information required by the statutes and regulations applicable to those programs under which funds will be expended. If any of the requirements for these latter programs are substantially the same, they may be met by a single assurance, certification, or narrative, as appropriate. The application need not meet the application or other requirements for programs which are sources of funds for the consolidated grant but under whose authority no funds will be expended.

(d) If after receiving a consolidated grant, an insular area wishes to use funds for a purpose authorized by an eligible program that is not included in the consolidated grant, or by an eligible program that was included in the grant but was not intended as a program under which funds would be expended, the insular area must submit an amended application indicating the proposed change and containing the assurances, certifications and other information applicable to that program.

§ 97.14 How will grant awards be made?

The Secretary, or his designee, will award a consolidated grant to each insular area that applies for a consolidated grant and meets the requirements of this Part and of the statutes and regulations applicable to the programs under whose authority the consolidated grant funds will be expended. As long as the amount requested does not exceed the amount for which the insular area is eligible under the programs that are being consolidated, the amount of the award will equal the amount requested in the application.

§ 97.15 For what purposes can grant funds be used?

Funds awarded under a consolidated grant must be used for purposes authorized by the statutes and regulations of the programs included in the consolidated grant. In its application for a consolidated grant the insular area is to indicate the amount of funds that will be allocated to the eligible programs.

§ 97.16 What fiscal, matching, and administrative requirements apply to grantees?

(a) An insular area receiving a consolidated grant must comply with the statutes and regulations applicable to the programs under which the funds are to be used, except as otherwise provided in this part.

(b) In regard to programs included in a consolidated grant, an insular area need not comply with any of the statutory or regulatory provisions requiring recipients to match federal funds with their own or other funds.

(c) A single report may be submitted in lieu of any individual reports that may be required under the programs included in a consolidated grant.

PART 100—INTERGOVERNMENTAL REVIEW OF DEPARTMENT OF HEALTH AND HUMAN SERVICES PROGRAMS AND ACTIVITIES

Sec.
100.1 What is the purpose of these regulations?
100.2 What definitions apply to these regulations?
100.3 What programs and activities of the Department are subject to these regulations?
100.4 [Reserved]
100.5 What is the Secretary's obligation with respect to Federal interagency coordination?

Sec.
100.6 What procedures apply to the selection of programs and activities under these regulations?
100.7 How does the Secretary communicate with state and local officials concerning the Department's programs and activities?
100.8 How does the Secretary provide states an opportunity to comment on proposed Federal financial assistance and direct Federal development?
100.9 How does the Secretary receive and respond to comments?
100.10 How does the Secretary make efforts to accommodate intergovernmental concerns?
100.11 What are the Secretary's obligations in interstate situations?
100.12 How may a state simplify, consolidate, or substitute federally required state plans?
100.13 May the Secretary waive any provision of these regulations?

Authority: Executive Order 12372, July 14, 1982 (47 FR 30959), as amended April 8, 1983 (48 FR 15887); sec. 401, Intergovernmental Cooperation Act of 1968, as amended (31 U.S.C. 6506); sec. 204, Demonstration Cities and Metropolitan Development Act of 1966, as amended (42 U.S.C. 3334).

Source: 48 FR 29200, June 24, 1983, unless otherwise noted.

§ 100.1 What is the purpose of these regulations?

(a) The regulations in this part implement Executive Order 12372, "Intergovernmental Review of Federal Programs," issued July 14, 1982 and amended on April 8, 1983. These regulations also implement applicable provisions of section 401 of the Intergovernmental Cooperation Act of 1968 and section 204 of the Demonstration Cities and Metropolitan Development Act of 1966.

(b) These regulations are intended to foster an intergovernmental partnership and a strengthened Federalism by relying on state processes and on state, areawide, regional and local coordination for review of proposed Federal financial assistance and direct Federal development.

(c) These regulations are intended to aid the internal management of the Department, and are not intended to create any right or benefit enforceable at law by a party against the Department or its officers.

§ 100.2 What definitions apply to these regulations?

"*Department*" means the U.S. Department of Health and Human Services (HHS).

"*Order*" means Executive Order 12372, issued July 14, 1982, and amended April 8, 1983 and titled "Intergovernmental Review of Federal Programs."

"*Secretary*" means the Secretary of HHS or an official or employee of the Department acting for the Secretary under a delegation of authority.

"*State*" means any of the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, Guam, American Samoa, the U.S. Virgin Islands, or the Trust Territory of the Pacific Islands.

§ 100.3 What programs and activities of the Department are subject to these regulations?

The Secretary publishes in the Federal Register a list of the Department's programs and activities that are subject to these regulations and identifies which of these are subject to the requirements of section 204 of the Demonstration Cities and Metropolitan Development Act.

§ 100.4 [Reserved]

§ 100.5 What is the Secretary's obligation with respect to Federal interagency coordination?

The Secretary, to the extent practicable, consults with and seeks advice from all other substantially affected Federal departments and agencies in an effort to assure full coordination between such agencies and the Department regarding programs and activities covered under these regulations.

§ 100.6 What procedures apply to the selection of programs and activities under these regulations?

(a) A state may select any program or activity published in the Federal Register in accordance with § 100.3 of this part for intergovernmental review under these regulations. Each state, before selecting programs and activities, shall consult with local elected officials.

(b) Each state that adopts a process shall notify the Secretary of the Department's programs and activities selected for that process.

(c) A state may notify the Secretary of changes in its selections at any time. For each change, the state shall submit to the Secretary an assurance that the state has consulted with local elected officials regarding the change. The Department may establish deadlines by which states are required to inform the Secretary of changes in their program selections.

(d) The Secretary uses a state's process as soon as feasible, depending on individual programs and activities, after the Secretary is notified of its selections.

§ 100.7 How does the Secretary communicate with state and local officials concerning the Department's programs and activities?

(a) For those programs and activities selected by a state process under § 100.6, the Secretary, to the extent permitted by law:

(1) Uses the state process to detemine views of state and local elected officials; and,

(2) Communicates with state and local elected officials, through the state process, as early in a program planning cycle as is reasonably feasible to explain specific plans and actions.

(b) The Secretary provides notice to directly affected state, areawide, regional, and local entities in a state of proposed Federal finanical assistance or direct Federal development if:

(1) The state has not adopted a process under the Order; or

(2) The assistance or development invovles a program or activity not selected for the state process.

This notice may be made by publication in the FEDERAL REGISTER or other appropriate means, which the Department in its discretion deems appropriate.

§ 100.8 How does the Secretary provide states an opportunity to comment on proposed Federal financial assistance and direct Federal development?

(a) Except in unusual circumstances, the Secretary gives state processes or directly affected state, areawide, regional and local officials and entities:

(1) At least 30 days from the date established by the Secretary to comment on proposed direct Federal development or Federal financial assistance in the form of noncompeting continuation awards; and

(2) At least 60 days from the date established by the Secretary to comment on proposed direct Federal development or Federal financial assistance other than noncompeting continuation awards.

(b) This section also applies to comments in cases in which the review, coordination, and communication with the Department have been delegated.

(c) Applicants for programs and activities subject to section 204 of the Demonstration Cities and Metropolitan Act shall allow areawide agencies a 60-day opportunity for review and comment.

§ 100.9 How does the Secretary receive and respond to comments?

(a) The Secretary follows the procedures in § 100.10 if:

(1) A state office or official is designated to act as a single point of contact between a state process and all Federal agencies, and

(2) That office or official transmits a state process recommendation for a program selected under § 100.6.

(b)(1) The single point of contract is not obligated to transmit comments from state, areawide, regional or local officials and entities where there is no state process recommendation.

(2) If a state process recommendation is transmitted by a single point of contact, all comments from state, areawide, regional, and local officials and entities that differ from it must also be transmitted.

(c) If a state has not established a process, or is unable to submit a state process recommendation, state, areawide, regional and local officials and entities may submit comments either to the applicant or to the Department.

(d) If a program or activity is not selected for review under a state process, state, areawide, regional and local officials and entities may submit comments either to the applicant or to the Department. In addition, if a state process recommendation for a nonselected program or activity is transmitted to the Department by the single point of contact, the Secretary follows the procedures of § 100.10 of this part.

(e) The Secretary considers comments which do not constitute a state process recommendation submitted under these regulations and for which the Secretary is not required to apply the procedures of § 100.10 of this part, when such comments are provided by a single point of contact, by the applicant, or directly to the Department by a commenting party.

(f) If an applicant receives comments under § 100.9(a)(2), (c) or (d) of this part, it must forward such comments to the Department with its application materials.

§ 100.10 How does the Secretary make efforts to accommodate intergovernmental concerns?

(a) If a state process provides a state process recommendation to the Department through its single point of contact, the Secretary either:

(1) Accepts the recommendation;

(2) Reaches a mutually agreeable solution with the state process; or

(3) Provides the single point of contact with such written explanation of the decision as the Secretary in this or her discretion deems appropriate. The Secretary may also supplement the written explanation by providing the explanation to the single point of contact by telephone, other telecommunication, or other means.

(b) In any explanation under paragraph (a)(3) of this section, the Secretary informs the single point of contact that:

(1) The Department will not implement its decision for at least ten days after the single point of contact receives the explanation; or

(2) The Secretary has reviewed the decision and determined that, because of unusual circumstances, the waiting period of at least ten days is not feasible.

(c) For purposes of computing the waiting period under paragraph (b)(1) of this section, a single point of contact is presumed to have received written explanation 5 days after the date such notification is dated.

§ 100.11 What are the Secretary's obligations in interstate situations?

(a) The Secretary is responsible for:

(1) Identifying proposed Federal financial assistance and direct Federal development that have an impact on interstate areas;

(2) Notifying appropriate officials and entities in states which have adopted a process and which select the Department's program or activity.

(3) Making efforts to identify and notify the affected state, areawide, regional, and local officials and entities in those states that have not adopted a process under the Order or do not select the Department's program or activity;

(4) Responding pursuant to § 100.10 of this part if the Secretary receives a recommendation from a designated areawide agency transmitted by a single point of contact, in cases in which the review, coordination, and communication with the Department have been delegated.

(b) The Secretary uses the procedures in § 100.10 if a state process provides a state process recommendation to the Department through a single point of contact.

§ 100.12 How may a state simplify, consolidate, or substitute federally required state plans?

(a) As used in this section:

(1) "Simplify" means that a state may develop its own format, choose its own submission date, and select the planning period for a state plan.

(2) "Consolidate" means that a state may meet statutory and regulatory requirements by combining two or more plans into one document and that the state can select the format, submission date, and planning period for the consolidated plan.

(3) "Substitute" means that a state may use a plan or other document

that it has developed for its own purposes to meet Federal requirements.

(b) If not inconsistent with law, a state may decide to try to simplify, consolidate, or substitute federally required state plans without prior approval by the Secretary.

(c) The Secretary reviews each state plan that a state has simplified, consolidated, or substituted and accepts the plan only if its contents meet Federal requirements.

§ 100.13 May the Secretary waive any provision of these regulations?

In an emergency, the Secretary may waive any provision of these regulations.

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Workers' Compensation Programs, Office of	**20, I**
World Agriculture Outlook Board	**7, XXXVIII**

Redesignation Table

At 45 FR 77367, November 21, 1980, a document was published transferring and redesignating certain regulations of the former Department of Health, Education, and Welfare to Title 34—Education, Subtitle A—Office of the Secretary, Department of Education.

The following table shows the relationship of the CFR section numbers under Parts 1 through 199 of Title 45 to their redesignation in Title 34.

45 CFR Old Part or Section Numbers	34 CFR New Part Numbers
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101	621
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105.1–105.507	408
105.601–105.607	525
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112	219
113	220
114	221
115	222
116	200
116a	201
116b	302
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119	208
120	206
121a	300
121b	305
121c	307
121d	309
121e	315
121f	318
121g	320
121h	324
121k	336
121m	301
121o	330
121p	331
121q	332
121r	333
122a	537
123	500
123a	501
123b	502
123c	503
123d	504
123e	510
123f	514
123g	520
123h	515
123i	505
130	770
131	773
132	776
133	777
134	774
136	776
137	606
146	655
146a	667
147	Removed
148	662
149	603
150	639
151	790
153	Removed
154	644
155	645
157	646
158	215
159	643
160f	745
161	295
161a	296
161b	752
161c	753
161e	755
161f	419
161g	757
161h	758
161l	647
161m	763
162	765
162a	766
162b	767
162c	768
163	440
163a	441
163b	442
163c	443
163d	444
164	726
166	425
166a	426
166b	431
166c	432
168	668
169	624
170	617
172	793

45 CFR Old Part or Section Numbers	34 CFR New Part Numbers
173	610
174	674
175	675
176	676
177	682
178	686
178a	695
179	648
180	270
182	631
182a	740
184	769
185	280
186	250
186a	251
186b	252
186c	253
186d	254
186e	255
186f	256
186g	257
186h	258
186i	259
186j	260
186k	261
186l	262
187	263
189	629
190	690
191	211
192	692
193	796
194	649
195	345
195a	346
195b	347
196	650
197	240
198	241
199a	605

Derivation Table

At 51 FR 34764, Sept. 30, 1986, a document was published by the Department of Health and Human Services which established in Title 42 a new Chapter V, Office of Inspector General—Health Care, consisting of Parts 1001 through 1004. This document also removed Part 101 from Title 45. A second document at 51 FR 34786, Sept. 30, 1986 amended Title 42, Parts 412, 420, 455, 466, 474, and 489. The following derivation table indentifies the sections of 42 CFR Chapter IV and 45 CFR Subtitle A from which the new 42 CFR Chapter V derives its content.

This table identifies the sections of 42 CFR Chapter IV and 45 CFR Subtitle A from which the new 42 CFR Chapter V derives its content. In the case of Title 45, all of the source sections were redesignated. In the case of 42 CFR Chapter IV, some of the source sections were redesignated, but others were retained in Chapter IV and duplicated in Chapter V.

New Section	Source Section
	42 CFR Chapter IV
1001.1	420.1
1001.2	420.2
1001.3	420.3
1001.100	420.100
1001.101	420.101
1001.102	420.102
1001.103	420.103
1001.105	420.105
1001.107	420.107
1001.109	420.109
1001.114	420.114
1001.115	420.115
1001.122	420.122
1001.123	420.123
1001.124	420.124
1001.125	420.125
1001.126	420.126
1001.128	420.128
1001.130	420.130
1001.132	420.132
1001.134	420.134
1001.136	420.136
1001.201	489.54
1001.211	489.55
1001.221	489.57
1001.301	412.48(c), (d), and (e)
1002.1	455.1
1002.2	455.2
1002.3	455.106
1002.200	455.200
1002.203	455.203
1002.204	455.204
1002.205	455.205
1002.206	455.206
1002.207	455.207
1002.208	455.208
1002.210	455.210
1002.211	455.211
1002.212	455.212
1002.213	455.213
1002.214	455.214
	42 CFR Chapter IV
1002.230	455.230
1002.232	455.234
1002.234	455.234
1002.301–1002.321	455.300
	45 CFR Subtitle A
1003.100	101.100
1003.101	101.101
1003.102	101.102
1003.103	101.103
1003.104	101.104
1003.105	101.105
1003.106	101.106
1003.107	101.107
1003.108	101.108
1003.109	101.109
1003.110	101.110
1003.111	101.111
1003.112	101.112
1003.113	101.113
1003.114	101.114
1003.115	101.115
1003.116	101.116
1003.117	101.117
1003.118	101.118
1003.119	101.119
1003.120	101.120
1003.122	101.122
1003.123	101.123
1003.124	101.124
1003.125	101.125
1003.126	101.126
1003.127	101.127
1003.128	101.128
1003.129	101.129
1003.130	101.130
1003.131	101.131
1003.132	101.132
1003.133	101.133
	42 CFR Chapter IV
1004.1	474.0

New Section	Source Section
	42 CFR Chapter IV
1004.10	474.30
1004.20	474.32
1004.30	474.34
1004.40	474.36
1004.50	474.38
1004.60	474.39
1004.70	474.40

New Section	Source Section
	42 CFR Chapter IV
1004.80	474.41
1004.90	474.42
1004.100	474.52
1004.110	474.54
1004.120	474.56
1004.130	474.58

List of CFR Sections Affected

All changes in this volume of the Code of Federal Regulations which were made by documents published in the FEDERAL REGISTER since January 1, 1973, are enumerated in the following list. Entries indicate the nature of the changes effected. Page numbers refer to FEDERAL REGISTER pages. The user should consult the entries for chapters and parts as well as sections for revisions.

For the period before January 1, 1973, see the "List of CFR Sections Affected, 1949–1963 and 1964–1972," published in three separate volumes.

1973

45 CFR

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Subtitle A	
5.3 Revised	22231
5.4 Revised	22231
5.11 Revised	22231
5.31 (b) amended; (c) revised	22231
5.32 (c) revised	22232
5.51 (c) revised	22232
5.61 Revised	22232
5.70—5.79 (Subpart F) Removed; new 5.70—5.74 (Subpart F) added	22232
5.82 Revised	22233
5.85 (a) revised	22233
5 Appendix revised	22233
15 Revised	8492
16 Added	9907
60.5 Removed	30658
60.12 (a) revised; (b) removed	30658
60.15 (a) removed	30658
60.17 (a), (e), (h), (i), (j), and (k) removed	30658
60.19 Removed	30658
67 Added	28291
73 Appendix C amended	17222
74 Added	26276
80 Heading revised	17979
80.1 Authority citation added	17982
80.2 Revised	17979
80.3 (b)(1)(vi) added; (b)(3) and (4) redesignated as (b)(4) and (5); new (b)(3) and (6) added; (c) and (d) revised	17979
Authority citation revised	17982
80.4 (a)(2), (b) and (d) revised	17980
Authority citation added	17982

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	38 FR Page
Subtitle A—Continued	
80.5 Introductory text, (a), (b), (e), and (h) revised; (i) and (j) added	17980
Authority citation added	17982
80.6 (b), (c), and (d) revised	17981
Authority citation added	17982
80.7 (b) amended	17981
Authority citation added	17982
80.8 Authority citation added	17982
80.9 (a) revised	17981
Authority citation added	17982
80.10 (e) and (f) revised; (g)(4) removed	17981
Authority citation added	17982
80.12 (a) and (c) revised	17981
Authority citation added	17982
80.13 Authority citation added	17982
80 Appendix A revised	17982
82.2 Revised	997
82.4 (b) revised	997
82.6 (a)(3) revised	997
82.10 Revised	997
82.14 Revised	997
82.15 Revised	997
82.22 Revised	998
Chapter I	
100—100c (Subchapter A) Heading added	30661
100 Added	30661
100a Added	30662
100b Added	30679
100c Added	30691
101—190 (Subchapter A) Heading added	30661
102.2 Removed	30658

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Chapter I—Continued

	38 FR Page
102.3 (e), (h), (k), (l), (p), and (r) removed	30658
(q) through (aa) redesignated as (r) through (bb); new (q) added	32243
102.4 (b)(1)(i) revised; (b)(5) and (6) added; (j) redesignated as (k); new (j) added	32243
102.42 (b) removed	30658
102.44 Removed	30658
102.122—131 Removed	30658
102.134 Removed	30658
102.144 Removed	30658
102.146—102.147 Removed	30658
102.154—102.155 Removed	30658
102.158 Removed	30658
103.2 Removed	30658
103.3 (b), (d), and (g) removed	30658
103.13 (a)(2), (3), (4), (5), (6), and (7) removed	30658
103.14 Removed	30658
103.16—103.17 Removed	30658
103.24 (a)(4), (5), (6), (7), (8), (9), and (10) and (c) removed	30658
103.27—103.28 Removed	30658
103.34—103.37 Removed	30658
103.41—103.61 (Subpart E) Removed	30658
107.1 (b), (c), (e), and (g) removed	30658
107.3—107.9 Removed	30658
111.1 (a), (d), and (e) removed	30658
112.1 (b) and (h) removed	30659
113.1 (b) and (f) removed	30659
114.1 (b), (g), and (v) removed	30659
115.3 (b) and (d) removed	36059
116.1 (e), (j), (k), (m), (t), (u), (x), (y) and (bb) removed	30659
116.21 (a), (b), (c), (d), and (e) removed	30659
116.26 Revised	17127
116.42 Removed	30659
116.46—116.48 Removed	30659
116.53 (a), (b), (c), and (e) removed	30659
116.54—116.57 Removed	30659
117.1 (c), (d), (e), (g), and (j) removed	30659
117.3 (l) removed	30659
117.13 Removed	30659
117.20 Revised	30659
117.21 (b) removed	30659
117.26—117.30 (Subpart E) Removed	30659
117.36 Removed	30659
117.39 Removed	30659

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	38 FR Page
117.43—117.45 Removed	30659
117.46 (c) removed	30659
118.2 (b), (e), (f), (g), (i), (q), (r), and (x) removed	30659
118.6 (e) removed	30659
118.18 (d) removed	30659
118.22 (f) removed	30659
118.31—118.34 Removed	30659
118.41—118.43 Removed	30659
118.45 Removed	30659
118.53 Removed	30659
118.55—118.58 Removed	30659
119.1 (c), (d), (e), (f), (g), (i), (k), and (l) removed	30659
119.7 Removed	30659
119.8 Introductory test revised	30659
119.21 Removed	30659
119.22 (b) removed	30659
119.23—119.28 Removed	30659
119.40—119.52 (Subpart D) Removed	30659
121.2 (a), (b-1), (d), (f), (g), (h), (i), (m), (n), (p), (q), (r), (t), and (u) removed	30659
121.3—121.12 Removed	30659
121.50—121.99 (Subpart A-1) Added	13740
121.56—121.60 Removed	30659
121.80 Removed	30659
121.82—121.84 Removed	30659
121.90 Removed	30659
121.99 Removed	30659
121.102 (d) and (g) removed	30659
121.106 (e) removed	30659
121.110 Removed	30659
121.127 (c) and (d) removed	30659
121.128 (d) removed	30659
121.131—121.133 Removed	30659
121.200—121.205 (Subpart C-1) Added	13742
121.230—121.240 (Subpart C-2) Added	13742
121.250—121.256 (Subpart C-3) Added	13744
121.270—121.277 (Subpart C-4) Added	13744
121.380—121.383 (Subpart D-2) Added	13745
121.400—121.426 (Subpart E) Added	13745
123.1 (d), (h), (i), (n), (p), (q), and (r) removed	30659
123.2 Removed	30659
123.3 Removed	30659
123.6 Removed	30659

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Chapter I—Continued

	38 FR Page
123.14 Removed	30649
123.21 Removed	30659
123.23—123.29 Removed	30659
123.35—123.38 (Subpart E) Removed	30659
123.44 (Subpart F) Removed	30659
124.1 (b), (c), (e), (f), (i), (j), and (k) removed	30659
124.4—124.7 Removed	30659
124.8 Amended	30659
124.15 (a), (c), and (d) removed	30659
124.16 Removed	30659
124.20—124.28 (Subpart D) Removed	30659
124.33—124.34 Removed	30659
125 Removed	13746
125.1 (c) removed	30659
129 Added	21924
129.1 (b), (e), (f), (h), (i), and (m) removed	30659
129.3 Amended	30659
129.6 (a) removed	30659
129.9 Removed	30659
129.10—129.19 Removed	30659
130.2 Removed	30659
130.3 (b), (d), (f), and (g) removed	30659
130.5 (b)(1) through (6) and (8) through (16) removed	30659
130.22 (c) removed	30659
130.31—130.44 Removed	30659
130.52 Removed	30659
130.53 Removed	30659
130.55 Removed	30659
131.1 Revised	30659
131.2 (e), (f) and (n) removed	30660
131.6 Removed	30660
131.10 Removed	30660
131.12—131.17 Removed	30660
132.1 Revised	30660
132.2 (b), (c), (d), and (e) removed	30660
132.5—132.12 Removed	30660
132.14 Removed	30660
132.16—132.27 Removed	30660
141.1 (e), (f), (g), (h), and (k) removed	30660
141.8 Removed	30660
141.11 (d)(4) removed	30660
141.12—141.18 Removed	30660
141.21-141.23 (Subpart E) Removed	30660
142.2 (c), (e), (f), (g), (j), (k), (l), (m), (n), and (p) removed	30660
144.2 (a) revised	15959

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	38 FR Page
(d), (e), (f), (v), (w), and (y) removed	30660
144.3 (a) revised	15959
144 Appendix A added	15959
145.1 (d), (e), and (i) removed	30660
147.2 (e) and (f) removed	30660
150.1 (f) removed	30660
151.2 (b), (d), (h), (j), (k), and (n) removed	30660
151.4 Removed	30660
151.5 (b) removed	30660
151.7 Removed	30660
151.8 Removed	30660
151.9 Removed	30660
151.11 Removed	30660
151.13—151.16 Removed	30660
151.18—151.23 Removed	30660
151.31—151.40 Removed	30660
151.42—151.44 Removed	30660
151.46—151.47 Removed	30660
155.2 (b), (d), and (g) removed	30660
155.3 Removed	30660
155.7 (c) and (f) removed	30660
155.9 (a) removed	30660
155.11—155.14 Removed	30660
160.2 (f), (q), (r), and (u) removed	30660
160.10 (a), (b), (f), and (g) removed	30660
160.11—160.14 Removed	30660
160.16—160.17 Removed	30660
160.19—160.22 Removed	30660
160 Appendix amended	30660
166 Revised	16133
166.2 Removed	30660
166.3 (f), (g), (h), and (k) removed	30660
166.16 (a) removed	36060
166.21 (a) removed	30660
166.22—166.31 Removed	30660
166.33—166.36 Removed	30660
166.43 Removed	30660
166.44 Removed	30660
166.46—166.47 Removed	30660
167 Added	16138
167.2 Removed	30660
167.3 (f), (g), (h), (k), and (l) removed	30660
167.7 (a) removed	30660
167.8—167.10 Removed	30660
167.11 (a) and (b) removed	30660
167.12—167.13 Removed	30660
167.15 Removed	30660
167.17—167.20 Removed	30660
167.24 Removed	30660

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Chapter I—Continued	38 FR Page
167.25—167.27 Removed	30660
167 Appendix A added	34560
170 Revised	14096
170.1 (f) and (l) removed	30660
170.2—170.4 Removed	30660
170.5 (b) removed	30660
170.6 (b)(1) and (2) and (c) removed	30660
170.8 Removed	30660
170.13 (a)(4) removed	30660
170.14 (b) amended	30660
170.18 (a) and (c) removed	30660
170.19 Removed	30660
170.45 Removed	30660
171.1 (h), (j), (p), and (q) removed	30660
171.4 (b) amended	30660
171.7 (b) removed	30660
171.8 Removed	30660
171.10—171.12 Removed	30660
173.1 (b), (d), (e), (g), and (i) removed	30660
173.14 Revised	30660
173.16 Removed	30660
173.23 Removed	30660
173.24—173.33 Removed	30660
173.37 Removed	30660
175.2 (d), (h), and (s) removed	30660
175.15 Removed	30660
175.16 (b) and (c) removed	30660
175.17 Removed	30660
175 Appendix A added	15960
176 Added	15960
177.1 (d) and (i) removed	30661
177.2 Revised	25
177.4 (c)(3)(xiv) added	1509
(c)(3)(xv) added	9669
(c)(3)(xvi) added	20072
(c)(3)(xvii) added	27935
177.10 Added	25
178.1 (d) and (i) removed	30661
180 Revised	16065
180.02 (a), (h), and (k) removed	30661
180.03 Removed	30661
180.04—180.06 Removed	30661
181.1 (a), (e), and (h) removed	30661
181.13—181.14 Removed	30661
181.16 Removed	30661
181 Appendix A removed	30661
185 Added	3452
185.02 (b), (c), (h), (l), and (m) removed	30661
185.03 Revised	30661
185.31—185.38 (Subpart D) Added	10094

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Chapter I—Continued	38 FR Page
185.44 (d)(3) revised	21646
185.51—185.56 (Subpart F) Added	10098
185.71—185.76 (Subpart H) Added	10101
185.81—185.85 (Subpart I) Added	10103
185.91—185.94 (Subpart J) Added	10104
185.95 (b)(1) and (3) revised	13563, 21647
185 Appendix A removed	30661
186—189 Added	18018
186.2 Amended	30661
186.31—186.34 (Subpart D) Removed	30661
187.2 Amended	30661
187.3 Added	30661
187.21 Introductory text revised; (e), (f), (g), (h), (i), and (j) removed	30661
187.31—187.34 (Subpart D) Removed	30661
188.3 Added	30661
188.15 Introductory text revised; (c), (d), (e), and (f) removed	30661
188.21—188.24 (Subpart D) Removed	30661
189 Added	27825
190.31—190.39 (Subpart C) Added	15419
190.41—190.48 (Subpart D) Added	15421

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45 CFR

	39 FR Page
Subtitle A	
5.3 Amended	28631
5.4 Amended	28631
5.31 (b) and (c) amended	28631
5.32 (a), (b) and (c) amended	28631
5.71 (b) and (c) redesignated as (c) and (d); new (b) added	28631
5.72 (d) amended	28631
5.85 (a) amended	28631
14.15 Removed	27322
25 Added	19478
46 Added	18917
60 Temporary rule added	9440
Chapter I	
100a.10 (a)(22) and (24) removed	19212

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Chapter I—Continued	39 FR Page
100a.400 Revised	19212
100b.10 (l) added	19213
101.10—101.13 (Subpart B) Added	19212
103 Revised	29363
103 Appendix B added	7423
Appendix A added	10566
118.2 (b), (e), (f), (g), (i), (q), (r), and (x) removed	17104
118 Appendix added	14345
121.2 (a), (b-1), (d), (f), (g), (h), (l), (m), (n), (p), (q), (r), (t), and (u) removed	17104
123 Revised	17965
124 Revised	13652
127 Added	41851
130 Revised	41711
131 Revised	40495
132 Revised	17540
133 Added	17546
144.4a Added	37384
149 Added	30042
151 Revised	22147
154 Added	14945
155.7 Revised	19216
158 Revised	22343
166.11 (a) revised	18074
166.44 Removed	17104
167 Revised	18390
167.3 (f), (g), (h), (k), and (l) removed	17104
169 Added	18650
170 Revised	26724
170.6 (b)(1) and (2) and (c) removed	17104
170.8 Removed	17104
171 Revised	12950
174 Added	10567
175.3a Revised	17547
175.14a Added	37385
176 Revised	37385
176.1 Corrected	37987
176.4 (b) amended	37987
176.16 (c) corrected	37987
176.20 (e)(3) corrected	37987
176.21 (a) corrected	37987
177.4 (c)(3)(xviii) added	1849
(c)(3)(xix) added	17104
(c)(3)(xx) added	25943
(c)(8)(xxi) added	36967
180.13 (a) revised	16886
180.22 (b)(1) revised	16887
180.23 (a) revised	16887
180.24 (a) revised	16887
183 Added	17842
185.71 Revised	13268

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Chapter I—Continued	39 FR Page
185.72 Revised	13268
185.73 Revised	13269
185.74 Amended	13269
185.75 Revised	13270
185.76 Revised	13270
185.91 (a) revised	13270
185.91-1 Added	17547
185.92 (b)(4) added	13270
185.92-1 Added	17548
185.93-1 Added	17548
185.94-1 Added	17549
185.95 (b)(1) and (3) revised	13270
186.22 Removed	22424
186.31—186.33 (Subpart D) Added	22424
187.21 Introductory text revised; (e), (f), (g), (h), (i), and (j) removed	17104
189 Revised	15481
190.1—190.5 (Subpart A) Added	39413
190.11—190.16 (Subpart B) Added	39415
190.16 Added	39415
190.31—190.38 (Subpart C) Revised	24473
190.41—190.47 (Subpart D) Revised	24475
190.51 (Subpart E) Added	39416
190.61—190.66 (Subpart F) Added	39416
190.71—190.86 (Subpart G) Added	41800
192 Added	19213

1975

45 CFR

Subtitle A	40 FR Page
5.3 Revised	26512
5.4 Revised	26512
5.11 Revised	26512
5.31 (a), (b), and (c) amended	26512
5.32 (b) and (c) introductory text revised	26512
5.34 Revised	26512
5.51 Revised	26512
5.53 Revised	26513
5.60 Revised	18998
5.61 Revised	18998
5.70 Revised	26513
5.71 (c) revised	18998
(a) revised	26513
5.72 (b) and (e) revised	18998

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123.14 (a) and (b) revised; (c), (d), and (e) added	26519
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123.16 (a) and (c) revised	26521
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130.16 (a)(2) amended	25013

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144.15 Added	22136
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185.13 (k) introductory text and authority and (1), (2) and (n) revised	25173
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74 Authority citation amended........44552
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190.35 (a)(2) revised; eff. 7-1-78 to 6-30-79	3912
190.39 (a)(5) and (c) added; eff. 7-1-78 to 6-30-79	3912
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123.14 (b)(5)(i) and (10) revised; (b)(7)(iii)(D), and (11) through (14) added; interim	18909
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